SZUTEST

Product Conformity Assessment Program Procedure

A) DOCUMENT APPROVALS

No	Definition	Action	Approved By	Date
1	Document approved	Approval	Nurgül Çınar	23.05.2025
2	Translation approved	Approval	Songül Ağar	20.05.2025

B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
10	Cl. 8.3.3.1 Audit Time Table has been added.	Improvement	23.05.2025	23.05.2025
9	A statement regarding transfer audits been added. General and editorial arrangements have been made.	Document Review & Improvement	22.04.2025	22.04.2025

5. Purpose and Scope

The purpose of this procedure is to determine the principles for carrying out conformity assessment activities for products within the scope of Regulation (EU) 2016/425 on Personal Protective Equipment.

6.Definitions

Ministry: Ministry of Labor and Social Security of the Republic of Türkiye

Conformity Assessment: All operations performed to determine the conformity of the product with the relevant technical regulation.

Audit Team: Personnel carrying out conformity assessment activities.

Team Leader: Lead auditor/technical expert with overall responsibility for managing the conformity assessment activity.

Certificate of Conformity: Written document prepared in case of positive results of the conformity assessment process

Nonconformity: The requirements of the Regulation (EU) 2016/425 on Personal Protective Equipment or it is the finding that is detected when any of the relevant harmonized standard requirements are not provided.

Minor Nonconformity: These are deviations that are not systematic and do not affect the outcome of the activity and the system in general, where any of the Regulation/Standards and/or company documentation requirements are not fully met, but the conformity of the product can be seen with the presence of objective evidence.

Major Nonconformity: It is the non-conformity that directly affects the activity that is not systematically implemented and/or that does not adequately define any of the Regulation/Standards and/or company documentation conditions or their subheadings, which may affect the continuous application of the system in general and/or negatively affects the service or product offered to the client to be met under the desired conditions.

Observation: These are the findings that are specified to assist the audit team and the audited organization in the next audit, and that define the issues that will not be considered as nonconformity but should be taken into consideration.

Nonconformity requiring follow-up audit: Major nonconformities that directly affect product safety and require field verification.

Manufacturer: It refers to a natural or legal person who manufactures a product or has a product designed or manufactured and markets the product under its own name or trademark or uses the product for its own purposes.

Extraordinary events and conditions: A situation that is beyond the organization's control, often referred to as a "force majeure" or "natural disaster". For example; war, strike, riot, political instability, geopolitical tension, terrorism, crime, epidemic or pandemic, flood, earthquake, malicious hacking, other natural or man-made disasters.

Effective Number of Personnel: The effective number of personnel consists of all personnel (permanent, temporary, and part-time) involved within the scope of certification, including those working on each shift.

7. Responsibilities

Department Manager, Technical Manager, Auditor and Technical Experts are responsible for the implementation of this procedure.

8. Process

8.1. Application and Agreement

Client requests received with the FR.PPE.01 Certification Application Form ((EU) 2016/425) are evaluated according to the PR.PPE.01 Personal Protective Equipment Regulatior Application Evaluation and Agreement Procedureand after mutual agreement is reached with the applicant, the FR.PPE.02 Product Certification Service Agreement ((EU)2016/425) is signed. Project information is saved in App.Szu software. The project numbers given to the work files in the system to be recorded on the server are given below;

Module B

- PPE-B-XXX (Numbered according to project order)

Module C2

- PPE-C2-XXX (Numbered according to project order)

Module D

- PPE-D-XXX (Numbered according to project order)

8.2 Conformity Assessment Program Types (Product Certification Modules)

Conformity Assessment Functions and Activities in Product Certification Program	**Product Certification Modules**

	B	C2	D
I. Selection			
Evaluation of the application, determination of relevant normative documents and signing of the contract, sample selection	X	X	X
II. Evaluation of Features			
Test	X+T	X+T	
Technical File Review	X	X*	
Inspection	X+M	X+M	
Management system audit			X+KS
III. Review			
Examining the evidence of compliance obtained	X	X	X
IV. Certification Decision			
Decision to grant and maintain the certificate, expand its scope, suspend or withdraw the certificate	X	X	X
V. Certification			
Issuance of the certificate	X	X	X
Issuance of a certificate for a product batch		X	X
Issuance of a certificatefor a product type	X	X	X
Granting of the right to use the certificate and CE marking for a product stack		X	X
Granting the right to use the Notified Body Identification number		X	X
VI. Surveillance		X	X
Inspection or testing of samples taken from the factory		X+T+M	
Management system audits			X+KS

*Technical File evaluation is not performed in cases where the EU Type Examination Certificate is issued by SZUTEST.

X: Indicates the necessity of application
+ T: In the evaluation to be carried out, the requirements of EN ISO/IEC 17025 Articles 6 and 7 (except article 7.9) apply in addition to the requirements of the EN ISO/IEC 17065 standard.
+ M: In addition to the requirements of the EN ISO/IEC 17065 standard, the requirements of EN ISO/IEC 17020 Articles 6.1.2, 6.1.3, 6.1.6, 6.1.7, 6.1.8, 6.1.9 and 6.1.10 shall be applied in the evaluation to be carried out.
+ KS: In the evaluation to be carried out, the requirements of Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and Articles 9.1, 9.2, 9.3, 9.4 and 9.6 of EN ISO/IEC 17021-1 shall be applied in addition to the requirements of the EN ISO/IEC 17065 standard.

8.3 Carrying out Conformity Assessment

While carrying out conformity assessment activities; the following instructions are followed in the evaluations of relevant product groups such as the evaluation of test results, the evaluation of product-specific standard requirements, and the evaluation of the conformity of the sample to the technical file.

- TL.PPE.01 Product Evaluation Instruction – Foot and Leg Protective Equipment
- TL.PPE.02 Product Evaluation Instruction – Equipment Providing Hand and Arm Protection
- TL.PPE.03 Product Evaluation Instruction – Face and Eye Protective Equipment
- TL.PPE.04 Product Evaluation Instruction – Hearing Protective Equipment
- TL.PPE.05 Product Evaluation Instruction – Head Protective Equipment
- TL.PPE.06 Product Evaluation Instruction – Respiratory System Protective Equipment
- TL.PPE.07 Product Evaluation Instruction – General Body Protective Equipment
- TL.PPE.08 Product Evaluation Instruction – Protective Equipment Against Falls from Heights
- TL.PPE.09 Product Evaluation Instruction – Protective Equipment Against Drowning

8.3.1 Assingment of Audit Team and Certification and Decision Committee

Following the signing of the contract, the Technical Manager selects Technical Experts/Auditors who are qualified in the relevant field in the FR.PPE.07 Personal Protective Equipment Regulation Personnel List and forms the audit team and assigns an impartial personnel to take part in the Certification Review and Decision Committee with the FR.25 Audit Team Certification Committee Assigning Form to follow the entire process from the application process to the review and to ensure file integrity. The assigned audit team and the determined dates are recorded in the FR.PPE.30 Personal Protective Equipment Regulation Planning Calendar. A personnel in the audit team cannot take place at the Certification Review and Decision Committee.

Only Turkish and English languages are used when carrying out conformity assessment activities. Markings on the product in Turkish and English are evaluated. Markings in other languages are not evaluated. When forming the audit team, the issue of impartiality is taken into consideration each year, and care is taken not to assign the same audit team for three consecutive years by checking the FR.PPE.30 Personal Protective Equipment Regulation Planning Calendar.

8.3.2 EU Type Examination ((EU) 2016/425 ANNEX V Module B)

After the audit team is formed, the Team Leader creates a FR.26 Audit Plan by making a 1,0 man/day audit plan, but this plan is not sent to the company. The audit team notification is made to the company via e-mail by the Team Leader or Technical Manager. The Audit Plan includes the examination of the technical file and the conformity of the sample to the technical file.

The technical file is prepared by the client in accordance with the FR.PPE.04 Technical File Content List in accordance with the PR.PPE.01 Personal Protective Equipment Regulation Application Evaluation and Agreement Procedure, in a way that demonstrates the conformity of the product with the requirements of the PPE regulation.

The conformity of the technical file is examined by the audit team and recorded with the FR.PPE.03 Technical File Evaluation Report.

During the technical file review, risk analysis evaluation is performed and recorded with the FR.PPE.03 Technical File Evaluation Report.
Adequate analysis and evaluation of risks is the responsibility of the manufacturer.
The manufacturer explains the identified risks and indicates the relevant sections of the standards/specification and the relevant evaluation method.
Example; analysis, review, testing etc. SZUTEST examines the records to ensure:
- To properly present the risks, the Essential Health and Safety Requirements specified in Annex II of the PPE regulation must be taken into account.
- Risks are correctly identified according to the application and PPE provided.
- It reflects the risks identified in the user manual provided and includes the relevant usage limitations as far as the requirements of the PPE Regulation are concerned.

A minimum number of samples are requested from the client according to the product groups. Excess samples are sent back to the client/disposed of. The number of samples to be requested is notified to the client by e-mail or contract.
Storing samples is not intended as a reference sample for future testing, so the product does not have to be stored under the designed storage conditions. Once the sample review is complete, the sample can be disposed of/returned to the customer.

The client sends the specified number of samples to SZUTEST in accordance with the standard specified in the FR.PPE.02 Product Certification Service Agreement or as notified tc the client by e-mail.
When the sample is delivered to SZUTEST; the conformity of the sample to the type specified in the technical file is examined with the product evaluation report in the instructions for the relevant product according to the product group and the sample's conformity to the technical file report forms.
If necessary, Technical Expert reviews are added as a record in the report appendix. Devices within SZUTEST are used in product reviews. These devices are tape measures and calipers.
If the sample does not comply with the technical file, the company is informed by filling out the FR.29 Nonconformity Report or by e-mail. Once the relevant situation is resolved, the evaluation form is completed.

Then, the control form prepared according to the standard of the product that is the basis for the application is filled by the audit team according to the product group. Document information is defined in the instructions for the relevant product.
Test reports submitted within the technical file are accepted under the following conditions:

- The laboratory performing the tests must be accredited according to EN ISO/IEC 17025 standard.
- In cases where the laboratory is not accredited by a national or international independent organization, positive results of the audits and evaluations carried out by a Technical Expert qualified by SZUTEST and trained in the EN ISO/IEC 17025 standard and SZUTEST Personnel competent in the EN ISO/IEC 17025 standard.
- Test reports were not issued more than 5 years ago

In case of any missing information in the technical file, the client will be informed in writing (via e-mail).
The technical file is obtained with approval from the client and archived by the relevant Technical Expert by initialing it or stamping it with the "Review" stamp. During the evaluation process, if any deficiencies remain unresolved, the Team Leader may issue an FR.29 Nonconformity Report, if considered necessary.

If test reports are not available, samples are requested in accordance with the content of the Technical File, in order to perform the necessary examinations/have them performed by a subcontractor laboratory, as specified in the FR.PPE.02 Product Certification Service Agreement ((EU) 2016/425) or by e-mail. Samples are sent by the client to SZUTEST or to the subcontractor laboratory specified by SZUTEST. The matters specified in the manufacturer's user manual are taken into consideration in sample transportation and storage conditions.

Test requests to subcontracted laboratories are made via the relevant laboratory's test request form or by e-mail.

The general principle for Module B certifications is as follows:

If a new colour or size is added to an issued Module B Certificate and the scope is extended, the individually defined tests are repeated. The test information is defined in the relevant product instructions.

- **If there is one model product and only one size within the scope of the Module B certification application;**

It is expected that all standard tests covered by the product have been performed. If there is more than one standard within the scope of the application, common tests are performed only once.

- **If there is one model product and more than one size within the scope of the Module B certification application;**

If the performance tests for the relevant types within the scope of the application are appropriate, they are tested in mixed sizes. If the size difference affects the conformity of the product to the technical conditions, it is carried out as a separate product. Care is taken to test the smallest and largest products.

- **If there is more than one model product and more than one size within the scope of the Module B certification application;**

If the materials used in the models within the scope of the application are declared to be completely the same for each model, common testing can be applied, if appropriate, in accordance with the requirements of the relevant standard. Tests that affect the performance of the product are performed separately for each size/model.
In order for the materials used to be considered the same;

- Each layer of the materials used in the models must be the same and the supplier of each layer must be the same.
- The weight of each material used in the models must be the same.
- If there is a situation such as laminated coating on the fabric, it is considered as a different model.

- **If there is more than one model product, more than one size and more than one color within the scope of the Module B certification application;**

Different colored products should be evaluated individually. The above application is valid for different models and sizes. Details are included in the relevant product instructions. Manufacturers wishing to affix the CE label to products classified as Category III of the categories specified in Annex I of Regulation (EU) 2016/425 on Personal Protective Equipment, must choose either Annex VII (Module C2) or Annex VIII (Module D).

8.3.3 Conformity to Type Based on Quality Assurance of the Manufacturing Process ((EU) 2016/425 ANNEX VIII Module D)

8.3.3.1 Assignment of Audit Team and Audit Planning

The audit team is formed as specified in Article 8.3.1. In Module D audits, the first pre-audit evaluation is made to confirm that the company is ready before the field audit. The Team Leader creates a FR.26 Audit Plan by making a 0,5 man/day audit plan, but this plan is not sent to the company. The audit team notification is made to the company by the Team Leader or Technical Manager via e-mail. Once the FR.PPE.21 Pre-Audit Evaluation Form – Module D (Annex VIII) ((EU) 2016/425) has been completed, the Technica Manager, if appropriate, forms the audit team for the on-site evaluation. In order to complete the relevant form, the team leader requests the following information from the company, if not available:

- Technical File
- Current certificates for the product, if any
- QMS documents
- Internal audit & MRM records
- Official documents

If a nonconformity that prevents the audit is detected, the Team Leader informs the company with the FR.29 Nonconformity Report. After the relevant nonconformities are eliminated, the Technical Manager forms the audit team for the field evaluation. The Team Leader prepares the FR.26 Audit Plan document, the FR.26 Audit Plan (and the resumes of the audit team upon request) is sent to the company at least 3 days before the audit. The approval of the audit team is requested from the company, if approval is not given, the company is requested to state the reason. The Technical Manager may change the audit team by taking the reasons into consideration. In case of a situation that is contrary to the provisions of the Privacy and Impartiality Agreement, the audit team must definitely be changed. A personnel in the audit team cannot serve on the Certification Review and Decision Committee.

The audit time is planned as 1,0 man/day for 1-5 model products, if the effective number of personnel also fits the table. The Team Leader may increase the audit time in the following cases:

- Having more than 3 production lines (0,5 man/day increase is made for every additional 2 production lines.)
- Having more than 5 product models (0,5 man/day increase is made for every additional 2 product models.)
- Speaking different languages and using interpreters
- Presence of different locations
- Presence of outsourced processes

The Team Leader may reduce the audit time in the following cases:

- Presence of similar processes
- The company has completed more than two certification cycles.
- The maturity of the company's quality management system
- High level of technology and automation presence

The audit increase/decrease period is defined on the FR.26 Audit Plan.
It is ensured that the audit time is not less than 1,0 man/day.

Relationship between Effective Number of Personnel and Audit Time is given below:

Effective Number of Personel	Initial Audit Time (man/day)		Surveillance Audit Time (man/day)
	Pre-Audit Evaluation Time	Site Audit Time	
1-5	0,5	1,0	1,0
6-10	0,5	1,5	1,0
11-15	0,5	2	1,0
16-25	0,5	2,5	1,0
26-45	1,0	3	1,5
46-65	1,0	4	1,5
66-85	1,0	5	2,0
86-125	1,5	5,5	2,5
126-175	1,5	6,5	3,0
176-275	2,0	7	3,0
276-425	2,0	8	3,5
426-625	2,0	9	3,5

For higher numbers of employees, IAF MD 5 is used in the calculation of the audit time.

8.3.3.2 Carrying out the audit

The audit consists of the following stages:

- Opening meeting
- Audit
- Audit Team meeting and reporting
- Closing meeting

8.3.3.3 Opening Meeting

The audit is carried out in the field begin with an opening meeting chaired by the Team Leader, attended by company officials and the audit team. In the opening meeting, the issues specified in the FR.27 Opening and Closing Meeting Record, the purpose and scope of the audit, the methods and procedures to be used and the FR.26 Audit Plan are discussed. If deemed necessary by the Auditor/Technical Experts, a quick site tour may be carried out with the organization representatives in order to make a preliminary situation evaluation for the location, process and products to be inspected and to collect preliminary information from the field. The hours of the items in the audit plan may be changed with the approval of the company and the audit team.

8.3.3.4 Audit

The audit is carried out in a way that meets all sections/processes and items specified in the FR.26 Audit Plan. Each audit team member is responsible for auditing the areas specified in the audit program and must inform the Team Leader in case the audit periods exceed the plan so that the necessary arrangements can be made. During the audit, each audit team member must record the findings, recommendations and other important points regarding the audit, such as the names of the persons audited, the procedure item numbers related to the findings, the name, code and description of the samples selected during the audit, in a way that ensures that the non-conformities and observations are detected based on sufficient objective evidence, on the FR.PPE.06 Audit Report - Module D (Annex VIII) ((EU) 2016/425). In this way, information regarding audit objectives, scope and criteria is collected and verified with appropriate sampling to become audit evidence. The methods used to collect information may be interviews, review of processes, practices, documents and records, field observations against defined practices, etc.

During the audit, the audit team evaluates the progress of the audit and exchanges information as needed. If findings are found that will cause problems in achieving the audit objectives or if an urgent and significant risk (such as security) occurs, the Team Leader determines the appropriate action and reports this to the Technical Manager and, if possible, to the client. Such an action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The decision is communicated to the Technical Manager by the Team Leader. If changes to the audit scope are considered, this is agreed upon with the client.

8.3.3.5 Audit Team Meeting

Following the completion of the audit, the audit team reviews the audit findings in a meeting among themselves and classifies any deviations from the standard conditions of the company quality management system, regulatory conditions and company documentation, and records them with the FR.29 Nonconformity Report. The audit team can evaluate non-conformities in two classes as Major (Big) and Minor (Small), and can also classify the findings as observations. Non-conformities can be based on the relevant Regulation or standards. Objective evidence should be included in the FR.29 Nonconformity Report.

8.3.3.6 Determination of Corrective Actions

All nonconformities are recorded with the FR.29 Nonconformity Report, supported by objective evidence documented by the audit team. In addition, the article of the standard or regulation that the nonconformity corresponds to is defined. Depending on the content of the recorded nonconformities, it is decided to evaluate them in the field or in the office. A follow-up audit is planned for the nonconformities that are decided to be verified in the field. For the certification decision, all non-conformities must be verified within 90 days. In case of force majeure, the company may request additional time by justifying. The evaluation of the period is made by the Certification Review and Decision Committee at the decision stage.

8.3.3.7 Preparation of Audit Report

After the audit is completed, the audit team prepares the Audit Report FR.PPE.06 - Module D (Annex VIII) ((EU) 2016/425) which includes the recommendation regarding certification. The Team Leader completes the report and prepares the decision. After the non-conformities are resolved, the Team Leader presents the entire file to the Certification Review and Decision Committee.

8.3.3.8 Informing the Company Representative

During the audit, the company is kept transparent and informed about the progress of the audit. If the audit lasts more than one day, interim closing meetings are held and summary information is provided.
In one-day audits, information about the findings is provided in the closing meetings.

8.3.3.9 Closing Meeting

After the completion of the audit, a closing meeting is held under the chairmanship of the Team Leader with the participation of company representatives, where the issues specified in the FR.27 Opening and Closing Meeting Record are discussed. The purpose of the closing meeting is to present the audit results, including the proposal regarding certification. Non-conformances are discussed with the company to ensure that the evidence is correct and the non-conformances are understood. Reports prepared for the company to formally accept the non-conformances are presented to the company representative by the Team Leader for approval. Following the presentation of the nonconformities to the company representative, the FR.29 Nonconformity Report is signed by the company representative as confirmation of the acceptance of the findings by the company. The Team Leader leaves a copy of the FR.29 Nonconformity Report with the company and provides the necessary information regarding the closure of the nonconformities found. The corrective action plan must be sent to SZUTEST by the company within 10 days and approval must be obtained. It cannot be submitted to the

Certification Review and Decision Committee for a decision before all major and minor non-conformances are closed in the initial certification audits and scope extension audits. The audit team cannot make any promises or commitments regarding the date of issuance of the certificate.

8.3.3.10 Surveillance Audits

8.3.3.10.1 These are periodic audits carried out by SZUTEST to verify that the company it has certified continues to comply with the certification conditions. Surveillance audits are carried out in 12-month periods, taking the certification date as reference. At least 3 months before the expiration of the certificate validity period, companies are contacted by the Planning Officer or under the coordination of the Technical Manager and a response is requested from the company. These companies are followed up via the FR.PPE.31 Certified Companies List and APP. If the company does not respond or does not request the maintaining of the certificate, the certificate loses its validity at the end of the validity period. This situation is notified to the companies in writing under the coordination of the Technical Manager. If there are any changes affecting the audit or the document, they are confirmed at this point and in the plan approval. If the first surveillance audit cannot be conducted within 12 months from the certification date, the company's certificate is suspended by the Technical Manager as of the date the 12-month period expires. The surveillance audit is planned within 3 months and if it is successful, the suspension is removed and the document is published. If the surveillance audit cannot be planned within 3 months, the document is canceled and notified in writing.

Requests for postponement from companies for subsequent surveillance audits may be evaluated by the Technical Manager, provided that the reason is stated, and for temporary situations (such as moving, fair, conference, business trip, heavy workload, temporary health problems, temporary halt in production and service) may be postponed for up to three months. The postponement request is received in writing (e-mail or fax). In surveillance audits, before major nonconformities are closed and the action plan for minor nonconformities is approved, it cannot be submitted to the Certification Review and Decision Committee for a decision. The audit team cannot make any promises or commitments regarding the date of issuance of the certificate.
The duration of surveillance audits cannot be less than 1,0 man/day.

8.3.3.10.2 Surveillance audits should include the following:
The purpose of surveillance is to ensure that the manufacturer fully complies with its obligations outside the approved quality assurance system.

8.3.3.10.3 SZUTEST carries out audits at least once a year to ensure that the company maintains and implements the quality assurance system. As a result of the audits, the company is given the Annex FR.PPE.06 Audit Report - Module D (Annex VIII) ((EU) 2016/425). SZUTEST may conduct unexpected audits of the manufacturing or assembly area During such audits, SZUTEST may, if necessary, conduct or have tests conducted to check the proper functioning of the quality assurance system and the product. The company is provided with the Annex FR.PPE.06 Audit Report - Module D (Annex VIII) ((EU) 2016/425).

8.3.3.10.4 When assigning the audit team that will conduct surveillance audits, at least one person from the audit team must be assigned in the relevant product area.

8.3.3.10.5 Special postponement requests from companies regarding surveillance audits due to force majeure reasons (such as natural disasters, epidemics) are evaluated by the Technical Manager and postponements may be granted for up to 6 months.

8.3.3.10.6 For surveillance audits, the company is contacted at least 3 months in advance, taking the surveillance period specified in the contract as reference. The Technical Manager determines the audit periods and the appropriate audit team in accordance with the audit period determination rules and forwards it to the audit team with the FR.25 Audit Team Certification Committee Assigning Form. In case of any objections to the assignments made by the audit team, the reasons are noted on the audit team assignment form and a new audit team is assigned by the Technical Manager. If the audit team does not object to the assignments made, the audit team and the company are contacted and the FR.26 Audit Plan prepared by the audit team leader and the resumes of the team members (if requested) are sent to the company at least 3 days before the audit. The company is asked for the approval of the audit team, if the approval is not given, the situation is conveyed to the Technical Manager with the reasons. The Technical Manager may change the audit team by taking the reasons into consideration.

8.3.3.10.7 When planning the surveillance audit, the audit history specified in FR.PPE.06 Audit Report - Module D (Annex VIII) ((EU) 2016/425) is taken as reference. The audit team audits all items on the checklist. FR.PPE.06 Audit Report - Module D (Annex VIII) ((EU) 2016/425) reviews the findings and evidence found in the previous year. Conducting the audit, reporting, closing and following up on non-conformities are carried out in the same way as in the certification audit.

8.3.3.10.8 On-site verification of non-conformities detected in the previous audit and closed without on-site verification, control of CE marking, brand and certificate usage are carried out during the surveillance audit. If a non-conformity is found as a result of on-site verification, it is evaluated as a major non-conformity by the audit team in the non-conformity report and the company is left for a follow-up audit regarding the non-conformity.

8.3.3.10.9 The final decision regarding the maintaining of the certificate belongs to the Certification Review and Decision Committee, as in the certification audit. If the non-conformities cannot be closed before the specified dates, the company's certificate is suspended by the decision of the Technical Manager. The company is notified of the situation in writing. The Certification Review and Decision Committee decides on the maintaining of the validity of the certificates of companies that close all non-conformities before the specified dates.

8.3.3.11 Certification Audits

8.3.3.11.1 Recertification audits are audits conducted to re-certify companies when the certificate period expires. At least 3 months before the certificate validity period expires, companies are contacted by the Planning Officer or under the coordination of the Technical Manager and a response is requested from the company. If the company does not respond or does not request the maintaining of the certificate, the certificate loses its validity at the end of the validity period. This situation is notified to the companies in writing under the coordination of the Technical Manager.

8.3.3.11.2 If a company wishes to be re-certified after the expiration of the certificate validity period, the application is treated as certification, not as recertification.

8.3.3.11.3 If the company requests a certificate renewal, a recertification audit is carried out. A new contract is made with the company in accordance with the pricing rules. The FR.PPE.01 Certification Application Form ((EU) 2016/425) is filled in by the company again, the old file number of the company is valid. Planning the recertification audit, assigning the audit team, performing the audit, reporting the audit, closing the nonconformities and making the certification decision are the same as in the certification audit. However,

provided that the recertification activities are completed, the certification decision can be made and the certificate can be activated within 6 months after the expiration of the certification period. The valid date on the certificate will be the recertification date or later and the previous certification cycle will be taken as basis during the validity period, otherwise the process will be considered as the first certification. During the application review phase of the recertification audits, the Technical Manager decides whether or not to complete the FR.PPE.21 Pre-Audit Evaluation Form - Module D (Annex VIII) ((EU) 2016/425) and makes the assignment accordingly.

8.3.3.11.4 During recertification, the nonconformities and corrective actions detected in the previous audit are examined. The audit scope, new documents, brand and certificate usage are checked and the process is carried out as in the surveillance audit. As a result of the audit, the evaluation is carried out as in the certification audit.

8.3.3.12. Transfer Audits

Certificate transfers are not carried out within the scope of Regulation (EU) 2016/425 on Personal Protective Equipment. Transfer applications are not accepted.

8.3.4 Internal Production Control Plus Type Conformity Subject to Supervised Product Testing at Random Intervals ((EU) 2016/425 ANNEX VII Module C2)

Type conformity, subject to internal production control plus product testing at random intervals, is part of the conformity assessment procedure, in which the manufacturer fulfils the obligations set out below and ensures and declares, within the framework of his exclusive responsibility, that the protective equipment concerned conforms to the type described in the EU Type Examination Certificate and fulfils the requirements of the Regulation applicable to these products. The manufacturer shall take all necessary measures to ensure that the production process and the monitoring it carries out conform to the type described in the EU Type Examination Certificate and the requirements of the Regulation applicable to these protective equipment.

Before starting production, the manufacturer shall provide all necessary information as defined below, in particular:

- Technical File
- Test reports
- EU Type Examination Certificate
- Documents and certificates describing all the systematic measures taken to ensure the conformity of the production processes and protective equipment with the type described in the EU Type-Examination Certificate.

The SZUTEST Technical Expert examines these documents to confirm their conformity with the EU-Type Examination Certificate before the start date of production. These documents are as follows:

1. Description of controls on the conformity of production methods and manufacturing of protective equipment
2. An audit document describing the appropriate evaluations and tests to be performed during production, together with the frequency with which they are performed and the relevant procedures;
3. Addresses of production and storage locations and the date production started

Prior to the Module C2 site audit, the FR.PPE.36 Pre-Audit Evaluation Form - Module C2 (Annex VII) ((EU) 2016/425) is completed by the Team Leader.

8.3.4.1 Assignment of Audit Team and Audit Planning

The audit team is formed as specified in Article 8.3.1. In Module C2 audits, if the Module B certificate is not issued by SZUTEST, a pre-audit assessment is carried out to confirm that the company is ready before the first field audit. The Team Leader prepares a 0.5 man*daily audit plan and creates an FR.26 Audit Plan, but this plan is not sent to the company. The audit team is notified to the company by the Team Leader or Technical Manager via e-mail. When the FR.PPE.36 Pre-Audit Evaluation Form - Module C2 (Annex VII) ((EU) 2016/425) is filled in, the Technical Manager, if appropriate, forms the audit team for the field assessment. In order to fill in the relevant form, the team leader requests the following information from the company if it is not available:

- Technical File
- If any, Existing certificates for the product
- Official documents

If a nonconformity that prevents the audit is detected, the Team Leader informs the company with the FR.29 Nonconformity Report. After the relevant nonconformities are eliminated, the Technical Manager forms the audit team for the field assessment. The Team Leader prepares the FR.26 Audit Plan document, FR.26 Audit plan (resumes of the audit team upon request) is sent to the company at least 3 days before the audit. The company is asked for the approval of the audit team, if approval is not given, the company is asked to state its reason. The Technical Manager can change the audit team by taking the reasons into consideration. In case of a situation that is contrary to the provisions of the Privacy and Impartiality Agreement, the audit team must definitely be changed. A personnel in the audit team cannot serve on the Certification Review and Decision Committee

Module C2 audit time is 0,5 man/day. It is planned as 1,0 man/day for 2-4 models. In addition to the increase in the number of models, the duration may be increased for the following reasons:

- Having more than 3 production lines
- Use of translator
- Having different locations
- Presence of externally sourced processes

Audit time cannot be less than 0,5 man/day.

8.3.4.2 Carrying out production site inspection

Conducting a production site inspection consists of the following stages:

- Openin Meeting
- Production Site Inspection and Sample Selection
- Audit Team meeting and reporting
- Closing meeting

8.3.4.3 Opening Meeting

Audits carried out in the field start with an opening meeting chaired by the Team Leader, attended by company officials and the audit team. In the opening meeting, the issues specified in the FR.27 Opening and Closing Meeting Record, the purpose and scope of the audit, the methods and procedures to be used and the FR.26 Audit Plan are discussed. If deemed necessary by the Auditor/Technical Experts, a quick field tour can be carried out with the organization representatives to make a preliminary assessment of the situation and collect preliminary information from the field for the location, process and products to be audited. The hours of the items in the audit plan can be changed with the approval of the company and the audit team.

8.3.4.4 Product Controls

The SZUTEST Technical Expert performs or ensures that protective equipment checks are performed on random samples at random time intervals determined by it in order to verify the quality of internal controls on the product, taking into account the technological complexity of the product and the production volume.
The controls consist of two steps;

8.3.4.4.1 The Technical Expert assigned for product controls and factory visits selects the samples at a location agreed upon with the company and records the process with the FR.PPE.16 Sampling Record Form and ensures that the samples are delivered to the laboratory.
The tests to be performed are determined by the Technical Expert and the Annex of the FR.PPE.16 Sampling Record Form is filled. Samples are taken in the number specified in the relevant tables.

Samples will be selected "at random" by the SZUTEST Technical Expert at a location agreed upon by the SZUTEST Technical Expert and the manufacturer (production site, importer, distributor, retail outlet or from existing stock).
The number of samples to be selected must be the same as that specified in the relevant standards. If the samples are packaged, the package will be selected according to the lot size and a sufficient number of samples will be randomly selected from the packages.

Samples should be selected in a way that represents the final product that can be offered to the market (after the last stage of production or from the warehouse). When taking samples, the process should be done randomly and homogeneously.
Samples must be taken with labels/markings that will ensure traceability (at least to the starting point of production). Sample selection is not made from a single point, but is taken in a mixed manner to represent the entire batch.
The matters specified by the manufacturer in the user manual are taken into consideration in sample transportation and storage conditions.

8.3.4.4.2 Annual Production Evaluation

The Technical Expert assigned for product controls and factory visits carries out inspections at the production site to assess the homogeneity of production and the conformity of the products to the technical file. FR.PPE.19 Internal Control of Production Form Module C2 (Annex 7) is filled in by the Technical Expert.

Based on the results of the tests, the FR.PPE.20 Module C2 Annual Surveillance Report is filled out by the Technical Specialist and submitted to the Technical Manager for approval. If the Technical Manager approves, the Module C2 Annual Surveillance Report is shared with the client.

Before the protective equipment is placed on the market by the notified body, a sufficient number of samples taken from the final protective equipment are examined and the relevant tests specified in the relevant parts of the harmonised standards and/or tests of equivalent nature specified in the relevant technical specifications are also carried out in order to check the conformity of the protective equipment with the type described in the EU Type Examination Certificate and the relevant requirements of this Directive.

If a protective equipment does not meet the acceptable quality level, SZUTEST takes the appropriate measures.

In Module C2 certifications, the tests performed for Module B certification are examined and the critical tests published in the relevant instructions, if any, and the tests with the weakest performance are determined by the Technical Expert. For tests with a 4-year cycle, the FR.PPE.33 Module C2 Annual Product Test Plan is prepared by the Technical Expert, taking into account the previous test reports. Since the 5th year Module B recertification process begins, the plan is prepared for 4 years.

If Module B certificate is issued by another NB, two scenarios are considered:

- Notification of the notified body is valid
- Notification of the notified body is not valid

If the Module B certificate is published by an NB whose notification is valid, it is checked whether there are ISO/IEC 17025 accredited test reports. If there is an accredited test report within the scope of ISO/IEC 17025, the tests to be applied in the routine are selected.
If there is no accredited test report within the scope of ISO/IEC 17025, an additional test can be added. If the Module B certificate is not published by an NB whose notification is valid, the accredited test reports are evaluated and these reports are processed as if the Module B certificate was published by SZUTEST, and the non-accredited tests are re-performed. If the Module B certificate is not published by an NB whose notification is valid and there is no accredited test report, the full test is applied.

If the Module B certificate is issued by SZUTEST:

Mixed sizes are used in samples sent for testing.

If there is a company applying with more than one model, if there is a declaration that the material used is the same, material tests are performed jointly.
The tests to be applied in all years are determined by the Technical Expert with the FR.PPE.33 Module C2 Annual Test Plan. The tests to be performed are notified to the client via the Test Plan or e-mail.

While creating the FR.PPE.33 Module C2 Annual Test Plan, the Technical Expert bases his/her product group test plans on the FR.PPE.48 Basic Health and Safety Requirements fo Personal Protective Equipment table.
Product group test plans:

- FR.PPE.49 Product Group Test Plan – Foot and Leg Protective Equipment
- FR.PPE.50 Product Group Test Plan – Hand and Arm Protective Equipment
- FR.PPE.51 Product Group Test Plan – Face and Eye Protective Equipment
- FR.PPE.52 Product Group Test Plan – Hearing Protective Equipment
- FR.PPE.53 Product Group Test Plan – Head Protective Equipment
- FR.PPE.54 Product Group Test Plan – Respiratory System Protective Equipment
- FR.PPE.55 Product Group Test Plan – General Body Protective Equipment
- FR.PPE.56 Product Group Test Plan – Protective Equipment Against Falls from Heights
- FR.PPE.57 Product Group Test Plan – Protective Equipment Against Drowning

In the first Module C2 audit and in others years, it takes into account at least the following points:

- When are tests performed for Module B certification?
- Whether the tests performed for Module B certification are included in the 4-year Module C2 test cycle
- Industry experience, relevant RfUs, CIRCABC notes, relevant meeting outputs
- Which Module C2 audit will be performed depending on the Module B certificate to which the product is subject, and which tests were performed in previous Module C2 audits,
- Whether previous Module C2 certificate(s), if any, were issued by SZUTEST
- Results of tests performed for Module B certification and where they were performed (whether performed in an accredited laboratory)
- Results of the tests on which the previous Module C2 certificate was based, if any, and where they were performed (whether performed in an accredited laboratory)
- Tests that are less than 1% higher/lower than the limit value will be included in the next Module C2 audit plan to be carried out.
- If the product is subject to more than one standard, the test plan is created by taking all tests into consideration and may be changed by the Technical Expert during the years of the tests.

If deemed necessary, the Technical Expert may revise the FR.PPE.33 Module C2 Annual Test Plan, taking into account the results of the previous year's tests, and inform the client.
Critical tests are included in Module C2 tests every year.
Critical test: These are tests that may cause changes in the product performance due to external factors such as raw materials and storage conditions, although the product is produced as specified in the technical file, not due to changes in the technical file (changes in design, raw materials, etc.), and they are tests related to the priority and features designed to provide protection for the product.
These tests are generally tests that define the protection class of the product, for example, hearing loss test for hearing protectors, mechanical strength test for head protectors, permeability/breathability tests for respiratory protectors, etc.

The FR.PPE.33 Module C2 Annual Test Plan is checked by the Documentation, Review and Decision Committee on the FR.PPE.32 Review and Decision Record, including the following:

- Are all tests performed for Module B included?
- Are tests that are at most 1% higher/lower than the cut-off value included in the first year?
- Have previous test selections been taken into account?

In Module C2 audits, samples can be taken by the audit team and sent to the subcontractor laboratory, or the samples selected by the audit team can be sent directly to the subcontractor laboratory under the supervision of the audit team.
Test requests to subcontracted laboratories are made via the relevant laboratory's test request form or by e-mail.

If the products tested within the scope of Module C2 fail the test by failing the standard requirements, an FR.29 Non-Conformity Report is issued. A follow-up audit is organized according to the activities resulting from the FR.29 Non-Conformity Report. The process for the follow-up audit is carried out as stated in Article 8.3.4.1. If the corrective action plan or corrective action evidence is not submitted within the specified period, the file is submitted to the Certification Review and Decision Committee by issuing a negative report (FR.PPE.20 Module C2 Annual Surveillance Report). The Technical Manager informs the company with the FR.PPE.20 Module C2 Annual Surveillance Report/letter abou the process has ended.

8.3.4.5 Audit Team Meeting

Following the completion of the audit, the audit team reviews the audit findings in a meeting among themselves and classifies any deviations from the standard conditions of the company quality management system, regulatory conditions and company documentation, and records them with the FR.29 Nonconformity Report. The audit team can evaluate non-conformities in two classes as Major (Big) and Minor (Small), and can also classify the findings as observations. Non-conformities can be based on the relevant Regulation or standards. Objective evidence should be included in the FR.29 Nonconformity Report.

8.3.4.6 Determination of Corrective Actions

All nonconformities are recorded with the FR.29 Nonconformity Report, supported by objective evidence documented by the audit team. In addition, the article of the standard or regulation that the nonconformity corresponds to is defined. Depending on the content of the recorded nonconformities, it is decided whether they will be evaluated in the field or in the office. A follow-up audit is planned for nonconformities that are decided to be verified on site. All nonconformities must be verified within 90 days for the certification

decision. In case of force majeure, the company may request additional time by justifying it. The evaluation of the period is made by the Certification Review and Decision Committee at the decision stage.

8.3.4.7 Informing the Company Representative

During the audit, the company is transparent and informed about the progress of the audit. If the audit lasts more than one day, interim closing meetings are held and summary information is provided. In one-day audits, information about the findings is provided in closing meetings.

8.3.4.8 Closing Meeting

After the completion of the audit, a closing meeting is held under the chairmanship of the Team Leader with the participation of company representatives, where the issues specified in the FR.27 Opening and Closing Meeting Record are discussed. The purpose of the closing meeting is to present the audit results, including the proposal regarding certification.

Nonconformities are discussed with the company to ensure that the evidence is correct and that the nonconformities are understood. The reports prepared for the official acceptance of the nonconformities by the company are presented to the company representative by the Team Leader for approval. Following the presentation of the nonconformities to the company representative, the FR.29 Nonconformity Report is signed by the company representative as confirmation of the acceptance of the findings by the company. The Team Leader leaves a copy of the FR.29 Nonconformity Report with the company and provides the necessary information regarding the closure of the nonconformities found. The corrective action plan must be sent to SZUTEST by the company within 10 days and approval must be obtained. It cannot be submitted to the Certification Review and Decision Committee for a decision before all major and minor nonconformities are closed in the initial certification audits. The audit team cannot make any promises or commitments regarding the date of issuance of the certificate.

8.3.4.9 Prenparation of Audit Report

After the audit is completed, the tests are successfully completed and any nonconformities are eliminated, the audit team prepares the FR.PPE.20 Module C2 Annual Surveillance Report, which includes a recommendation regarding certification. The Team Leader presents the entire file to the Certification Review and Decision Committee.

8.3.4.10 Other matters

When planning an audit in the years following the first year of Module C2 certificate, the process is carried out from the beginning by contacting the companies 3 months in advance. FR.PPE.36 Pre-Audit Evaluation Form - Module C2 (Annex VII) ((EU) 2016/425) is not filled out after the first year.

In cases published by SZUTEST, the applicant company must havec the Module C2 certificate within 1 year after the publication of the Module B certificate. Otherwise, if there is a contractual use of the NB number 2195, the necessary actions must be initiated to stop it. For planning, communication must be made 3 months before the end of 1 year. If the company declares that it does not produce or has received a Module C2 certificate from another organization, the validity of the Module B certificate continues. If the company declares that it does not produce, the company is informed that it must be notified at the first production. If it is known that it does not have a Module C2 certificate despite producing, the Module B certificate is suspended and the company is informed. Depending on the action to be taken by the company, the certificate is canceled or can be removed from suspension and a Module C2 audit can be performed. This decision belongs to the Technical Manager.

8.4 Other Situations Related to the Conformity Assessment Process

8.4.1 Stopping the Audit

The stopping of the conformity assessment activity can only occur if the following conditions are met:

- If it is determined that the requirements or legal sanctions related to the product within the scope of conformity assessment are not fulfilled
- If the conditions during the conformity assessment adversely affect or endanger the health of the audit team
- If serious problems are detected in the implementation of the system that prevent the maintaining of the conformity assessment and it is understood that a follow-up audit is inevitable (Under these circumstances, the suspension of the conformity assessment is an exceptional case and should be used as a last resort. In such cases, the renewal of the conformity assessment is mandatory)
- If there are serious problems in accessing records related to the relevant personnel, relevant department or job, product or service, or if a bribe is offered.
- In addition, if the company requests the suspension of the conformity assessment due to company-related reasons, the conformity assessment can be suspended on condition that it is repeated.

When the Team Leader decides to stop the conformity assessment, he/she must contact the company representative and explain the reason. During the decision-making phase, the Team Leader must consult the Technical Manager when necessary. The Team Leader calls the company's senior management to a meeting to explain the reason for stopping the conformity assessment. If the company's request for certification is still valid, it is stated that a conformity assessment will be repeated later, provided that the relevant nonconformity is eliminated. All details regarding the suspension of the conformity assessment must be stated in the report. The relevant report is sent to the company in writing.

8.4.2 Tracking of Detected Nonconformities

The company representative is requested to send the FR.29 Nonconformity Report to SZUTEST within 10 working days by describing the necessary activity to eliminate the non-conformity and the activity to prevent recurrence. The Technical Expert checks, verifies and signs that the activity specified in the form is sufficient to eliminate the non-conformity and prevent recurrence and complies with the given time periods. However, if it is understood that the activity described by the company is not sufficient to prevent recurrence of the non-conformity, the Non-Conformity Report is returned to the company without approval, with a reason given, to be reviewed again by the Technical Expert.

The maximum period allowed for the implementation of correction and corrective actions to close all non-conformities is 90 days from the date the non-conformity was recorded, regardless of the magnitude of the non-conformity (the period to be determined in the recertification audit must be earlier than the date the certificate expires). A file decision cannot be submitted before all non-conformities are closed. If there is a force majeure, the company may request additional time for corrective action and SZUTEST may grant this period up to a maximum of 90 days.

8.4.3 Closing Nonconformities with Follow-Up

Follow-up is planned for nonconformities that require verification in the field. The assignment and planning process for follow-up is carried out as in the normal conformity assessment process.
Follow-ups are carried out by the Technical Expert who served as the Technical Expert in the first assessment, as much as possible. If the corrective actions are found appropriate in follow-up audits, the certification phase is passed in the certification and recertification audits, and the maintaining of the certificate is ensured on surveillance audits.

8.4.4 Changes Occurring in Certified Products
In case of any change in the certification agreement, this change must be evaluated by SZUTEST by following the steps below.

1. Submits to SZUTEST using the FR.30 Certificate Change Request Form. In case of scope expansion, the FR.PPE.01 Certification Application Form ((EU) 2016/425) can b used.
2. The change is evaluated by the Technical Manager and the necessary technical or legal documentation is requested from the company.
3. The relevant documents sent by the client are reviewed by the Technical Manager. The Technical Manager decides according to the content of the change. An administrative assessment is made using the FR.30 Certificate Change Request Form. If there is a technical change request, the effects of the changes on the basic safety requirements of the regulation are checked. Changes that may cause deviations from the conditions specified in the basic requirements can be checked by performing the necessary tests and examinations in the laboratory. If the Technical Manager decides that an audit team needs to be formed, the process is carried out as described in article 8.3.1. In changes approved with the FR.30 Certificate Change Request Form, the FR.PPE.32 Review and Decision Record is not prepared again.
4. FR.PPE.02 Product Certification Service Agreement ((EU) 2016/425) is renewed by the Technical Manager if necessary.

8.4.5 File Contents
The certified files must contain the records in the excel table located in the "Files" tab of this procedure.

8.4.6 Storage of Records
All file records and samples are archived for 10 years. Files with a certificate are archived.

8.5 Subcontractor Determination Rules
It is carried out in accordance with PR.26 Subcontracter Applications Procedure.

8.6 Review and Decision
It is carried out in accordance with the PR.PPE.03 Certification Processes Procedure.

8.7 Reporting and Certification
It is carried out in accordance with the PR.PPE.03 Certification Processes Procedure.

8.8 Remote Control
8.8.1 This article is covered in the conformity assessment processes. Remote auditing techniques cannot provide the same outputs as on-site audits in all cases. For this reason, SZUTEST's primary approach is to conduct audits on-site. The period between subsequent certification/recertifcation dates and the audit date cannot exceed 15 months. However, if SZUTEST decides that on-site audits are not applicable due to extraordinary events and conditions, it may use remote auditing techniques to achieve the same purpose as on-site audits.

8.8.2 The level of applicability of remote auditing techniques can be determined according to the structure of the organization, the level of cooperation with SZUTEST, the risk of the organization's activities, certification experience, complaints and objections, and the initial certification and surveillance outputs if previously certified.

8.8.3 Remote audits are not applied in the initial certification audit. However, they can be used as part of the initial certification audit when deemed necessary. Care is taken to have at least one team member on site, even if he/she is a candidate auditor. After the extraordinary events and conditions have ended, field audits are carried out. If the extraordinary events and conditions continue, the certification process is continued until the situation ends.

8.8.4 For surveillance audits; due to extraordinary events and conditions, remote audit techniques may be preferred in accordance with Article 8.9.2. After the extraordinary events and conditions are over, field audits are carried out by the same audit team.

8.8.5 The audit team, including the opening and closing meetings, must have access to the remote connection of the management representative/factory production control officer. The audit team can hold interim meetings by disabling the audited party's access when necessary. Each audit team member and the audited party officials share audit records electronically.
Before the audit, a trial connection should be established and the parties should verify the compliance of the connection conditions of the audited party and the audit team. Before, during and after the audit, the audited party shall electronically transmit the documents and records that the audit team must review during the audit. These documents and records will be stored electronically on the SZUTEST server for a period of 10 years. The reporting of the audit, findings and applications shall be carried out and completed in accordance with articles 8.3, 8.4, 8.5, 8.6, 8.7, 8.9 and 8.10.

8.8.6 If the audited party cannot maintain the processes specific to this audit technique during the implementation of the remote audit or if the audit team cannot perform the remote audit sufficiently, the remote audit may be repeated, a new remote audit may be conducted for the remaining parts, or an on-site audit may be conducted, depending on SZUTEST's decision.

8.9 Temporary alternative emergency measures and arrangements for on-site audits
These temporary alternative extraordinary measures include the following principles and regulations:
Postponement of on-site surveillance audits due to force majeure.

Replacing on-site audits with remote audits using the most advanced Information and Communication Technologies available in accordance with information security and data protection legislation.
Off-site evaluation of all relevant and necessary documents/records by SZUTEST.
The possibility of using temporary alternative extraordinary measures for on-site inspections should be carefully evaluated, documented and implemented by SZUTEST on a case-by-case basis using a risk-based approach. In particular, the risk assessment determining the possibility of using these alternative measures should take into account the experience gained with the organization to be certified. For example, for organizations with a history of numerous and/or critical non-conformances, taking such temporary measures in relation to production/operational control may have an impact on the organization's compliance. However, in these cases, an alternative measure such as an on-site audit should be implemented as a temporary measure after the travel restrictions have been lifted. In order to assess which alternative extraordinary measure is most suitable, SZUTEST should evaluate the manufacturer's files regarding the situation and activities related to the audit in question, such as the area to be audited, the quality management system and the level of compliance with previous audits.

First of all, the organization should be contacted and the following information should be evaluated with the Information and Evaluation Form for audits to be Conducted by the Technical Manager within the Scope of FR.PPE.37 Temporary Extraordinary Measures.
Does the organization have a history of numerous and/or critical nonconformances or critical weaknesses in the previous audit report or critical processes that are recommended for review in the next audit?
Has a "Follow-up or suspension audit" been conducted in the organization's recent past?
When will the organization be able to operate normally?
When can the organization ship or perform products or services defined under the current certification scope?
Will the organization need to use alternative production and/or distribution sites? If so, are they currently within the scope of the current document or will they need to be evaluated?
Does the certified organization have a disaster recovery plan or emergency response plan? Has the certified organization implemented this plan and is it effective?
Will some of the operations and/or services performed or products shipped be subcontracted to other organizations? If so, how will the activities of other organizations be controlled by the certified organization?
To what extent has the functioning of the management system been affected?
Has the certified organization conducted an impact assessment?

A control definition that the organization has the necessary infrastructure to support the use of the proposed ICT. In cases where postponement cannot be justified, the Technical Manager and Department Manager should evaluate what alternative emergency measures should be taken. (e.g. remote audit; off-site document review; conference calls with relevant organization personnel). For remote audits, both SZUTEST and the manufacturer must have and install the necessary information and communication technologies or tools. (e.g. web conferences with document sharing, audits of production lines).
The confidentiality of intellectual property rights must be protected. SZUTEST must clearly document and communicate such requirements for its audits, together with its auditors, including the necessary data protection and cybersecurity measures, which must be shared prior to and within such audits. The technological capability of the organization to enable such an audit to be conducted must be verified by the audit team prior to the audit. Competent Authorities may request to observe/witness such remote audits through existing and established information and communication technologies or tools.
When creating the audit plan, SZUTEST must coordinate with the manufacturer the review period of the areas in the inspection plan, together with the overall duration of the audit , to ensure that this alternative is used effectively. The audits plan must also clearly state which alternative emergency measures will be used and what will be carried out remotely. When preparing audit reports, SZUTEST must clearly state that the audit is carried out remotely and also state the method(s) used for these audits.
Remote surveillance audits should cover all surveillance tasks that can be verified remotely, including on-site review of all documents that would normally be evaluated on-site.

8.9.1 Informing the Competent Authority

All deviations from the certification/conformity assessment programme must be justified, documented and made available to the Competent Authorities upon request. Notifications are made as described in PR.15 Communication Procedure.

8.9.2Mandatory Check Before Audits to Remote Control

Suitability for remote auditing: The suitability / authorization of the standard and/or relevant article for remote auditing should be checked.
The organisation's past experience: Check that the results of previous audits, recent restructuring or a long absence of on-site audits do not disqualify the client for a remote audit.
Technical feasibility: It should be checked whether the clients are suitable for remote auditing, considering the availability of the necessary ICT infrastructure. It should be checked whether the connection has been tested before the audit.

Audit Team Preparation: Auditors or technical experts who will participate in remote audits should have the ability to understand and use information and communication technologies used to obtain information and communication technologies when using ICT. They should be knowledgeable about ICT and its impact on the validity and limitations of information collected using this methodology. They should be aware of the risks, opportunities and impacts of ICT used on the validity and impartiality of information collected.
Remote audit duration: Check that the planned duration complies with the maximum duration allowed considering the audit scope. If ICT is used for audit/assessment purposes, the total audit/assessment duration should be taken into account when planning, as additional planning may be required that may affect the audit/assessment duration.

8.9.3 Matters to be Considered When Performing an Audit

The planned approach is approved by the auditor in the audit planning and then in the opening meeting.
During a remote audit, the security and confidentiality of information transmitted electronically or electronically is particularly important when using ICT for audit/assessment purposes.
It may not be possible to record the entire audit process during the audit. However, at least the opening and closing meetings, as well as other audit team-approved calls/video recordings of the audit should be recorded.
The use of applications on the auditor's computer that are not suitable for ICT at the same time should not be allowed.
It is highly recommended to use security/privacy tools, i.e. customization screens, headsets, etc. and use a separate room. It is preferable to use a client invitation when using

tools such as Skype, Zoom, etc. Audit report: The Audit Report should clearly describe the extent to which an ICT was used in conducting the audit and the effectiveness of the ICT in achieving the audit objectives.
The Audit Report is filled with the records of the people who participated in the remote audit.
During the implementation of the remote audit, all necessary precautions should be taken by the organization and the audit team to ensure the confidentiality of the audit. All necessary audit documents should be filled in accordance with the relevant procedures.

8.9.4 ICT Methods That Can Be Applied in Audits

Information and communication technologies are the use of technology to collect, store, retrieve, process, analyze and transmit information. It includes software and hardware such as smartphones, handheld devices, laptops, desktops, drones, video cameras, wearable technology, artificial intelligence and others. ICT can be suitable for both local and remote monitoring/assessment.
Examples of ICT use during audits/assessments may include, but are not limited to:
- Meetings via teleconferencing facilities including audio, video and data sharing
- Review/assessment of documents and records via synchronous (real-time) or asynchronous (if applicable) remote access
- Recording of information and evidence via still video, video or audio recordings
- Providing visual/audio access to remote or potentially dangerous locations

During audits, the Audit Team is required to use reliable communication tools approved by SZUTEST, such as Skype, Snagit, Google, Microsoft, Zoom. Communication tools not approved by SZUTEST cannot be used.

8.9.5 Prohibited Applications

- Remote audits in public places (e.g. train, cafe, etc.)
- Remote audits in a room with other people who are not part of the audit team.
- It is forbidden to store records obtained during the audit on personal computers other than those registered with SZUTEST.