

Product Conformity Assessment Program Procedure

A) DOCUMENT APPROVALS

No	Definition	Action	Created By	Date
1	Document approved	Approval	Nurgül Çınar	26.12.2023
2	Translation approved	Approval	Çağla Tufanç	26.12.2023

B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
22	The final report within the voluntary scope has been revised as FR.ATEX.49 (G).	Publication of FR.ATEX.49 (G) form.	26.12.2023	26.12.2023
21	The audit increase/decrease periods required for conformity assessment activities are defined.	Internal audit result CPA numbered 2023-112	31.08.2023	31.08.2023
20	It has been defined in the articles 8.3.2, 8.3.7 and 8.3.8 that if the technical file is missing, the customer will be informed with the FR.ATEX.04 form.	Improvement work.	11.07.2023	11.07.2023
19	No revision has been made in the English version of the document.	.	28.03.2023	28.03.2023
18	The places that say "Voluntary Type Examination" have been changed to "Voluntary Attestation Of Compliance". Transferred to IQMemo program. Millennium last revision definition: Where it says Industrial Department has been revised as Construction and Equipment Safety Department.	Improvement work on voluntary certifications. Transition to the new program. Millennium last revision reason: Renamed department to Department of Construction and Equipment Safety.	26.01.2023	26.01.2023

5. Purpose and Scope

The purpose of this procedure is to describe the conformity assessment activities from receiving the applications of customers requesting certification within the scope of the Regulation on Equipment and Protective Systems Used in Potentially Explosive Atmospheres 2014/34 / EU, up to the reporting and certification process.

6. Definitions

Ministry: Ministry of Industry and Technology

Conformity Assessment: All procedures carried out to determine the conformity of the product to the relevant technical regulation.

Certificate of Conformity: A written document issued in the event of a positive result of the conformity assessment process.

Nonconformity: It is the finding that is detected when any of the requirements of 2014/34 / EU Regulation on Equipment and Protective Systems Used in Potentially Explosive Atmospheres or the relevant harmonized standard requirements are not met.

Nonconformity requiring follow-up inspection: Nonconformities that directly affect product safety and require verification in the field.

Possible explosive atmosphere: It is an explosive atmosphere due to its location and operating conditions.

Explosive environment: It is a mixture formed by gas, vapor, fog and dust of flammable substances with air under atmospheric conditions and can be completely flammable in contact with any ignition source.

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

Equipment / product: Machines, assemblies, fixed or mobile devices, which are designed for production, transportation, storage, measurement, control and energy conversion and / or material processing and that can cause an explosion with their own possible ignition source and are located separately or together, control components, their means of use and detection or prevention systems.

Components (components): Any part that is necessary for the safe operation of equipment and protective systems, but does not have an independent function.

Protective systems: These are devices other than equipment components that are separately available on the market for use as stand-alone systems, intended to immediately stop newly started explosions and / or limit the impact area of the explosion.

Group I equipment: These are the parts that are valid for equipment to be used in underground parts of mines and used in aboveground facilities that may pose a possible danger by gas and / or flammable dusts of such mines, and include equipment categories M1 and M2.

Group II equipment: It is the parts that include 1, 2 and 3 equipment categories, which are valid for equipment to be used in other places where danger may occur due to explosive atmospheres.

Technical Regulation Officer: The person responsible for the management of activities related to the conformity assessment process.

Technical Expert: Personnel who are planned within the scope of conformity assessment activities, perform tests, inspections and / or inspections and present inspection and / or inspection results to the technical regulator.

Team Leader: It is the Technical Expert determined and appointed in case the audit team consists of more than one person.

ICT: Information and Communication Technology. Information and communication technologies are the use of technology to collect, store, receive, 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.

7. Responsibilities

Construction and Equipment Safety Department Manager, ATEX Unit Manager, Technical Regulation Officer and Technical Experts are responsible for the implementation of this procedure.

8. Method

8.1 Application and Contract

Customer requests received with the FR.ATEX.01 Conformity Assessment Application Form are evaluated according to the Evaluation of PR.ATEX.01 Application and the Contract Procedure. And with the approval of the customer, the Conformity Assessment Proposal and Contract is signed according to FR.ATEX.02 ATEX Regulation.

8.2 Conformity Assessment Program Types (Product Certification Modules)

Compliance in the Product Certification Program	Product Certification Modules								
	A	B	C1	D	E	F	G	Voluntary	
Evaluation Functions and Activities									
I. Selection									
Receiving the documents based on certification.	X	X	X	X	X	X	X	X	X
II. Determination of Properties									
Technical file review		X	X	X	X	X	X	X	X
Test		X + T	X + T			X + T	X + T	X + T	
Inspection		X + M	X + M				X + M	X + M	
Management system audit				X + KS	X + KS				
III. Review									
Examination of the evidence of conformity obtained		X	X	X	X	X	X	X	X
IV. Certification Decision									
Decision to issue and maintain the certificate, to extend its scope, to suspend or withdraw the certificate.	X	X	X	X	X	X	X	X	X
V. Truth Statement, Licensing									
Issuance of the document	X	X	X	X	X	X	X	X	X
Granting the right to use certificate and CE Mark	X		X	X	X	X	X		
VI. Surveillance									
Inspection or testing of samples in the manufacturer.			X + T						
Management system audits				X + KS	X + KS				

+ T: In the evaluation, the requirements of EN ISO / IEC 17025 Clause 5 are applied 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, EN ISO / IEC 17020 clauses 6.1.2, 6.1.3, 6.1.6, 6.1.7, 6.1.8., 6.1.9. and the requirements of 6.1.10 apply.

+ KS: In the evaluation, the requirements of Clause 9 of EN ISO / IEC 17021-1 are applied in addition to the requirements of the EN ISO / IEC 17065 standard.

8.3 Performing Conformity Assessment

8.3.1. Technical Expert Assignment

Following the signing of the contract, at least 1 technical expert is appointed by the technical regulation officer who will follow the whole process from the application process to the review. The maximum number of days of technical experts to be appointed is based on the following schedule.

2014/34 / EU Equipment and Protective Systems Used in Potentially Explosive Atmospheres	Annex 3-Module B	Technical File Review and Reporting 3 to 28 man / day between.
		Mechanical Tests Per Test at least 1 man / day
		Electrical Tests; Change according to the requirements of the Protection Type shows. (half day to 28 days)
		Completion of Review Report and Certification 2 man / day.
2014/34 / EU Equipment and Protective Systems Used in Potentially Explosive Atmospheres	Annex 4-7 Module D-E	The number of ATEX certified products of the manufacturer up to 2 2 man / day (half a day for each new type)
2014/34 / EU Equipment and Protective Systems Used in Potentially Explosive Atmospheres	Annex 5 ? Module F	For each product test 1 man / day
2014/34 / EU Equipment and Protective Systems Used in Potentially	Annex 6-	

Explosive Atmospheres	Module C1	For each product test 1 man / day
2014/34 / EU Equipment and Protective Systems Used in Potentially Explosive Atmospheres	Annex 9-Module G	Technical File Review and Reporting 3 to 28 man / day between.
		Mechanical Tests Per Test at least 1 man / day
		Electrical Tests; Change according to the requirements of the Protection Type shows. (half day to 28 days)
		Completion of Review Report and Certification 2 man / day.
2014/34 / EU Equipment and Protective-Systems Used in Potentially Explosive Atmospheres Voluntary Attestation Of Compliance	Voluntary	Technical File Review and Reporting 3 to 28 man / day between.
		Mechanical Tests Per Test at least 1 man / day
		Electrical Tests; Change according to the requirements of the Protection Typeshows. (half day to 28 days)
		Completion of Review Report and Certification 2 man / day.

Audit periods can be increased/decreased by the Auditor/Team Leader in the following cases:

The audit periods can be increased for Modules D and E in the following cases:

- The number of Atex certified products is more than 2 (an increase of 0,5 man/day is made for each new type.)
- Speaking different languages and using a translator
- Availability of different locations,
- The existence of outsourced processes
- The number of employees involved in Ex production is more than 100 employees (an increase of 0,5 man/day is made for each 25 employee.)

The audit periods can be decreased for Modules D and E in the following cases:

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

The audit periods can be increased for Module C1 and F in the following cases:

- Use of translator,
- Having different locations,
- The existence of outsourced processes

The audit periods can be increased for Module B and Voluntary Type in the following cases:

- Group family certification included more than 10 model (an increase of 1 man/day is made for each 10 model in Technical File Review)
- The number of protection types included in the certification as well as gas and dust environments. (an increase of 1 man/day is made for each protection excludes the i type, 3 man/day is made for the i type of protection in Technical File Review.)
- Use of translator
- Having different locations

The audit periods can be increased for Module G in the following cases:

- Number of the serials more than 5 serial (an increase of 1 man/day is made for each 5 serial.)
- Number of the part list included in assemblies more than 20 part lists (an increase of 1 man/day is made for each 20 part list.)
- Use of translator
- Having different locations

The audit increase/decrease period is defined on the FR.26 Audit Plan.

8.3.2. EU Type Examination Module (2014/34 / AB ANNEX-3) -Module B

Technical file, by the customer, of the product; The FR.ATEX.04 Technical file is prepared according to the content list in accordance with the PR.ATEX.01 Application Evaluation and the contract procedure to demonstrate the compliance with the requirements of the ATEX regulation.

The technical expert, who will evaluate the conformity of the technical file, is appointed by TDS with the FR.25 Audit Team Certification Committee Assignment Form.

The Technical Expert creates the FR.26 Audit Plan and then performs the evaluation of the technical file according to the FR.ATEX.04 Technical File Content List. In case the technical file is missing, the customer is informed with the FR.ATEX.04 Technical File Content List.

In case the tests are performed by the customer, the test reports are requested from the customer together with the technical file. In the institutions where the Test Report is made, the EN ISO/IEC 17025 Accreditation is primarily questioned, if the relevant institution has the scope of accreditation, the laboratory that submits the relevant report is accepted. It is questioned with the Control Form. During the audit, the records of the year of the test reports are also examined. If the laboratory is not accredited and the result of the inspection carried out by Szutest is negative, the submitted test reports are not accepted and the customer is notified in writing. When applicable, the laboratory's sampling registration form to ensure that the sample sent to the laboratory and the sample submitted to SZUTEST during the conformity of the sample to the technical file are the same sample, if the tests to be performed due to the requirements of the standards and regulations in the technical file submitted by the manufacturer, when applicable, meet the above-mentioned requirements. is examined. In cases where these tests cause damage to the product, this condition cannot be applied.

The reports of the appropriate laboratory are examined. It is recorded with the FR.ATEX.11. Test Result evaluation form made by the subcontractor or the customer. In case the tests have not yet been carried out by the customer and will be done during the application process to SZUTEST, the FR.ATEX.03 Mandatory Tests List is filled by the SZUTEST technical specialist and submitted to the customer with an additional contract. This situation is explained in article 8.3 of PR.ATEX.01 Application Evaluation and Contract Procedure. The costs related to the mandatory tests and the information of the subcontractor laboratories, if they are to be used, are notified to the customer in the contract. In this case, the assigned SZUTEST technical specialist before sending the samples to the laboratory records the information that will provide traceability on the sample and ensures that it is transmitted to the laboratory. This situation is recorded in the FR.ATEX.08 Sample Request Form. After the tests are carried out the test result made by the FR.ATEX.11 subcontractor or the customer is evaluated and recorded with the evaluation form.

Relevance of the technical file; It is examined by technical experts and recorded with the FR.ATEX.07 Standard Conformity Report of the Technical File. Control form prepared according to the protection type of the product, which is the basis of the application, together with the inspection report (FR.ATEX.14, FR.ATEX.17, FR.ATEX.18, FR.ATEX.19, FR.ATEX.20, FR.ATEX.21 , FR.ATEX.46) are filled in by the technical expert.

After the conformity of the technical file is approved, one or more samples suitable for the content of the technical file are requested with the FR.ATEX.08 Sample Request Form. If the sample is too large to be sent, the FR.26 Inspection Plan is filled and sent to the customer and an on-site inspection is made on the specified date. While the technical expert evaluates the conformity of the sample to the technical file, if he is going to use the manufacturer's devices during the tests, he/she makes the evaluations in order to check whether the device is suitable for the purpose of the test and whether the calibration reports and evaluations are done at a sufficient level. It records the checks made in the FR.ATEX.10 Test Report. If the equipment he evaluates is not suitable, he does not perform the inspection. When the sample is sent to SZUTEST or the assigned technical expert goes for on-site inspection; FR.ATEX.09 Sample Compliance Report with Technical File and FR.ATEX.10 Test Report are published. In case the sample does not comply with the technical file, the company is informed.

As a result of all these reports, the FR.ATEX.49 Product Conformity Evaluation Final Report is prepared by the Technical Expert.

After the evaluation processes are completed by the technical expert, the review and certification process is carried out in accordance with the PR.ATREX.04 Certification Procedures.

All the steps described above for the Annex-3 (Module B) certification process are specified in the TL.ATEX.12 instruction.

8.3.3. Conformity to Type Based on Quality Assurance of the Manufacturing Process (2014/34 / AB ANNEX 4) -Conformity to the type based on Module D and Product Quality Assurance (2014/34 / AB Annex 7) -Module E

İf the manufacturer has a product certified within the scope of 2014/34 / EU module B; In order to print the CE mark on its product;

Module D for Group I, M1 and Group 2 category 1 equipment

Manufacturer can apply under Module E for Group I, M2 and Group 2 category 2 equipment.

The manufacturer explains the steps he takes to ensure and declare that the product conforms to the type specified in the Production Quality Assurance certificate and fulfills the relevant requirements of the Regulation.

The manufacturer must establish an approved quality assurance system for the equipment in question. An application must be made to SZUTEST in accordance with the PR.ATEX.01 Application Evaluation and Contract Procedure for the evaluation of the quality system.

The quality system of the related equipment; It must ensure the conformity of this product with the requirements of the 2014/34 / EU directive and the conformity of these products with the type defined in the EU type examination certificate.

All elements, requirements and provisions fulfilled by the manufacturer; systematic and written instructions, procedures and principles should be filed regularly. The quality system file, quality programs, plans, handbooks and records should be appropriate and understandable.

The audit of the customer's quality assurance system is carried out according to the requirements of the EN 80079-34 standard and the appropriate protection type requirements stipulated by the standard.

In Module D inspections, detailed examinations are made on the basis of all production sites and all products. In Module E examinations, on the other hand, an examination is made on the basis of the product that is the basis for EU type examination.

The preliminary evaluation of the QMS basic documentation prepared by the manufacturer according to the technique and EN 80079-34 is

recorded with the FR.ATEX.32 Module D / E Pre-Evaluation Form.

If the pre-evaluation is sufficient, the FR.26 Audit plan is sent to the company for field audit.

Technical Experts; With the FR.ATEX.12.80079-34 Quality Assurance System Review Report, it checks that the customer's quality system includes an adequate definition of the following,

- a) The quality objectives of the management and the structure, responsibilities and authority of the organization regarding the quality of the product,
- b) Manufacturing processes to be used, quality control and quality assurance techniques and systematic activities,
- c) the inspection, testing to be made before, after and during the manufacturing and the frequency of their application,
- d) Quality records such as inspection reports, test information, calibration information, reports on the qualifications of the relevant personnel, etc.,
- e) The method of ensuring the desired quality of the product and monitoring the effective functioning of the quality system.

The manufacturer provides SZUTEST with all necessary information and in particular quality system documents consisting of quality records such as inspection reports and test information, calibration data, reports on the qualifications of the relevant personnel, allowing SZUTEST to enter the manufacturing, inspection, test and storage facilities for inspection purposes.

If there is incompatibility, FR.29. It is sent to the company with the nonconformity form.

Follow-up of nonconformity is made according to the criteria specified in articles 8.7.2 and 8.7.3.

After the nonconformities are closed, the certification process is carried out in accordance with the PR.ATREX.04 Certificate Transactions Procedure.

8.3.4. Conformity to type based on product verification (2014/34 / AB Annex-5) -Module F

If the manufacturer has a product certified within the scope of 2014/34 / EU module B; To print the CE mark on its product, it can apply under Module F for Group 1, M1 and Group 2 category 1 equipment.

This module is a manufacturer's; It explains the conformity assessment procedure that it provides and declares at its sole responsibility to conform to the type specified in the EU type examination document.

The manufacturer takes all necessary measures to ensure that the manufacturing process complies with the type of equipment specified in the EU type examination certificate and the relevant requirements of the Regulation.

The technical expert appointed by the technical regulation officer examines each product one by one, conducts the relevant test to check the compliance with the relevant requirements of the Regulation and prepares the FR.ATEX.10 Test Report.

After the tests are completed, the review and certification process is carried out in accordance with the PR.ATREX.04 Certificate Transactions Procedure.

8.3.5. Compliance with the Type Based on Controlled Product Testing and Internal Control of Production (2014/34 / AB ANNEX-6) - Module C1

If the manufacturer has a product certified within the scope of 2014/34 / EU module B; In order to print the CE mark on its product, it can apply under Module C1 for Group 1, M2 and Group 2 category 2 equipment.

This module describes the conformity assessment procedure where a manufacturer ensures and declares the conformity of the product to the type specified in the EU type examination document at his sole responsibility.

The manufacturer takes all necessary measures to ensure that the manufacturing process complies with the type of equipment specified in the EU type examination certificate and the relevant requirements of the Regulation.

The manufacturer or a person on its behalf conducts one or more tests on one or more specific properties for each individual product. These tests are carried out under the supervision of SZUTEST.

Certificate validity period is 1 year. The assigned technical expert goes to the manufacturer's inspection to review the test reports made / commissioned by the manufacturer once a year during the validity period and accompany the tests.

The technical expert prepares the FR.ATEX.10 Test Report for the tests he has observed during the field inspection.

After the tests are completed, the review and certification process is carried out in accordance with the PR.ATREX.04 Certificate Transactions Procedure.

8.3.6. Submission of Technical File within the Scope of Internal Production Control Module (2014/34 / EU ANNEX 8-Article 15.1.b. (2))

This module describes the conformity assessment procedure in which the manufacturer fulfills the obligations regarding the technical file, manufacturing and CE marking and the manufacturer provides and declares the relevant products under his sole responsibility.

The manufacturer should prepare and have a technical file.

Technical file, by the customer, of the product; The FR.ATEX.04 Technical file is prepared according to the content list in accordance with the PR.ATEX.01 Application Evaluation and the contract procedure to demonstrate the compliance with the requirements of the ATEX regulation.

Manufacturer; It takes the necessary measures to ensure that the products produced during and after the manufacturing phase comply with the technical file and the relevant requirements of the regulation.

Following the signing of the contract, the manufacturer submits the technical file to SZUTEST. SZUTEST keeps the technical file for 10 years.

8.3.7. Compliance Module Based on Unit Verification (2014/34 / EU ANNEX-9) -Module G

The customer applies within the scope of this module for products to be produced once and in a limited number. In this case, SZUTEST states the serial numbers or range of the products on the document it provides.

Technical file, by the customer, of the product; The FR.ATEX.04 Technical file is prepared according to the content list in accordance with the PR.ATEX.01 Application Evaluation and the contract procedure to demonstrate the compliance with the requirements of the ATEX regulation.

The technical expert, who will evaluate the conformity of the technical file, is appointed by TDS with the FR.25 Audit Team Certification Committee Assignment Form.

In case the technical file is missing, the customer is informed with the FR.ATEX.04 Technical File Content List.

The suitability of the technical file; It is examined by technical experts and examined with the Standard Conformity Report of the FR.ATEX.07 Type Design / technical file. Harmonized standard control form regarding the protection type of the product is used in the report annex. If the product is compound equipment (if it consists of more than one exproof equipment), these control forms will not be used since there will be no protection type on the label.

After the approval of the suitability of the technical file, the assignment of the technical experts assigned to inspect the product on site and carry out the necessary tests is done with the FR.26 Audit Plan.

FR.ATEX.29 during product inspection or in office environment with data collected or taken. ANNEX 9 Product Inspection Report is filled by technical experts. The control form related to the protection type of the product is used in the report annex. If this is a composite equipment, all exproof certified equipment on the equipment is evaluated by showing in FR.ATEX.29 ANNEX 9 Product Inspection Report.

If the tests are made by SZUTEST, the FR.ATEX.10 Test Report is published. In case the tests are carried out by the customer, test reports are requested from the customer. In the institutions where the Test Report is made, the accreditation of EN ISO / IEC 17025 is primarily questioned, if the relevant organization has an accreditation scope, the laboratory that submitted the relevant report is accepted, if it does not have an accreditation, its compliance with the requirements of EN ISO / IEC 17025 Accreditation is questioned with FR.289 17025 Experiment Laboratory Control Form by the competent personnel of SZUTEST. During the audit, the year's records of the test reports are also examined. The reports of the laboratory found appropriate are taken into examination.

The evaluation of the test results made by the subcontractor Laboratory or made by the customer is included in the FR.ATEX.11 Test result evaluation report.

In case of nonconformity detected during on-site inspection of the product, the company is informed with FR.ATEX.29 ANNEX 9 Product Inspection Report. When the nonconformities are eliminated, FR.29 Nonconformity report is filled.

As a result of all these reports, the FR.ATEX.49 Product Conformity Evaluation Final Report is prepared by the Technical Expert.

After the tests are completed, the review and certification process is carried out in accordance with the PR.ATEX.04 Certificate Transactions Procedure.

All the steps described above for the Annex-9 (Module G) certification process are specified in TL.ATEX.12 instruction.

8.3.8. Voluntary Attestation Of Compliance

Technical file, by the customer, of the product; The FR.ATEX.04 Technical file is prepared according to the content list in accordance with the PR.ATEX.01 Application Evaluation and the contract procedure to demonstrate the compliance with the requirements of the ATEX regulation.

The technical expert, who will evaluate the conformity of the technical file, is appointed by TDS with the FR.25 Audit Team Certification Committee Assignment Form.

The Technical Expert creates the FR.26 Audit Plan and then performs the evaluation of the technical file according to the FR.ATEX.04 Technical File Content List. In case the technical file is missing, the customer is informed with the FR.ATEX.04 Technical File Content List.

In case the tests are performed by the customer, the test reports are requested from the customer together with the technical file. In the institutions where the Test Report is made, the EN ISO/IEC 17025 Accreditation is primarily questioned, if the relevant institution has the scope of accreditation, the laboratory that submits the relevant report is accepted. It is questioned with the Control Form. During the audit, the records of the year of the test reports are also examined. If the laboratory is not accredited and the result of the inspection carried out by Szutest is negative, the submitted test reports are not accepted and the customer is notified in writing. When applicable, the laboratory's sampling registration form to ensure that the sample sent to the laboratory and the sample submitted to SZUTEST during the conformity of the sample to the technical file are the same sample, if the tests to be performed due to the requirements of the standards and regulations in the technical file submitted by the manufacturer, when applicable, meet the above-mentioned requirements. is examined. In cases where these tests cause damage to the product, this condition cannot be applied.

The reports of the appropriate laboratory are examined. It is recorded with the FR.ATEX.11. Test Result evaluation form made by the subcontractor or the customer. In case the tests have not yet been carried out by the customer and will be done during the application process

to SZUTEST, the FR.ATEX.03 Mandatory Tests List is filled by the SZUTEST technical specialist and submitted to the customer with an additional contract. This situation is explained in article 8.3 of PR.ATEX.01 Application Evaluation and Contract Procedure. The costs related to the mandatory tests and the information of the subcontractor laboratories, if they are to be used, are notified to the customer in the contract. In this case, the assigned SZUTEST technical specialist before sending the samples to the laboratory records the information that will provide traceability on the sample and ensures that it is transmitted to the laboratory. This situation is recorded in the FR.ATEX.08 Sample Request Form. After the tests are carried out the test result made by the FR.ATEX.11 subcontractor or the customer is evaluated and recorded with the evaluation form.

Relevance of the technical file; It is examined by technical experts and recorded with the FR.ATEX.07 Standard Conformity Report of the Technical File. Control form prepared according to the protection type of the product, which is the basis of the application, together with the inspection report (FR.ATEX.14, FR.ATEX.17, FR.ATEX.18, FR.ATEX.19, FR.ATEX.20, FR.ATEX.21 , FR.ATEX.46) are filled in by the technical expert.

After the conformity of the technical file is approved, one or more samples suitable for the content of the technical file are requested with the FR.ATEX.08 Sample Request Form. If the sample is too large to be sent, the FR.26 Inspection Plan is filled and sent to the customer and an on-site inspection is made on the specified date. While the technical expert evaluates the conformity of the sample to the technical file, if he is going to use the manufacturer's devices during the tests, he/she makes the evaluations in order to check whether the device is suitable for the purpose of the test and whether the calibration reports and evaluations are done at a sufficient level. It records the checks made in the FR.ATEX.10 Test Report. If the equipment he evaluates is not suitable, he does not perform the inspection. When the sample is sent to SZUTEST or the assigned technical expert goes for on-site inspection; FR.ATEX.09 Sample Compliance Report with Technical File and FR.ATEX.10 Test Report are published. In case the sample does not comply with the technical file, the company is informed.

As a result of all these reports, the FR.ATEX.49 (G) Product Conformity Evaluation Final Report is prepared by the Technical Expert.

After the evaluation processes are completed by the technical expert, the review and certification process is carried out in accordance with the PR.ATEX.04 Certification Procedures.

8.4. General Information Before Examination

All measurement equipment used in inspection activities must have been calibrated according to the PR.25 Device, Equipment and Hardware Management Procedure. Information on the measurement equipment / measuring equipment used during the inspections and the calibration certificate should be defined in the test report. In the case of the use of non-SZUTEST equipment, evidence that it meets the requirements of clause 8.5.2 of the PR.25 Device, Equipment and Hardware Management Procedure should be retained.

While the technical expert evaluates the conformity of the sample to the technical file, if he is going to use the manufacturer's devices during the tests, he/she makes the evaluations in order to check whether the device is suitable for the purpose of the test and whether the calibration reports and evaluations are done at a sufficient level. It records the checks made in the FR.ATEX.10 Test Report. If the equipment he evaluates is not suitable, he does not perform the inspection.

During the inspection process to be carried out, the necessary occupational safety measures must be taken by the customer, depending on the inspection site. The danger defined in TL.08 Occupational Health and Safety Rules Instruction and the measures to be taken should be taken into consideration by the Technical Expert.

If the applicant has produced equivalent solutions other than the solutions specified in the harmonized standard in order to ensure the basic safety rules, the evaluation of the measures arranged for these equivalent solutions is carried out by the Technical Expert.

Before inspection, SZUTEST requests from the manufacturer to have the following components ready for the relevant inspections for the product / products covered by the inspection.

8.5. Surveillance Audits (Module D, E, C1)

Surveillance audits are planned at 12-month intervals in order to evaluate the continuity of the system, but the frequency of the audit can be increased in line with the customer complaints received by SZUTEST, the degree of nonconformities and the opinions of the certification team. The first surveillance audit date to be performed after the first certification is planned based on the certification decision date, not to exceed 12 months. In case of excess, the suspension process is initiated by the Technical Regulation Officer. The deviation from the planned audit date is maximum +3 months in the surveillance audits to be carried out after the 1st surveillance audit and the surveillance audits to be carried out after the certification renewal audits. Justified reasons (such as Moving, Fair, Conference, Business Trip, Intensive Workload, Temporary Health Problems, Temporary Production and Service Stoppage) are requested from the certified customer for the postponement requests. However, if the deviation exceeds the specified period, it can be postponed with the decision of the committee, the deferment must be within the specified calendar year.

- Since a new audit report or certificate is issued to the company as a result of Module E and Module D audits, surveillance audits are planned so as not to exceed the validity period of the certificate.
- While planning the surveillance audit, the audit history specified in the certification audit report is taken as reference. Performing the audit, reporting and appropriate
- Closing and tracking of nonconformities are carried out as in the certification audit.
- On-site verification of minor nonconformities detected in the previous audit and approved corrective action plans, control of the use of CE mark, brand and certificate are carried out during the surveillance audit. If a nonconformity is found as a result of on-site verification, the nonconformity report is evaluated by the audit team as nonconformity that requires follow-up audit and the company is left for follow-up audit.
- The final decision regarding the maintenance of the certificate belongs to the certification committee as in the certification audit. If the

nonconformities that require follow-up inspection cannot be closed before the specified dates, the certificate of the company is suspended with the decision of the Technical Regulation Officer. The company is notified in writing. In case the regulatory action plans regarding nonconformities that do not require follow-up audit are approved by the assigned technical expert, the certification committee decides on the continuation of the validity of the documents.

- Scope extension for Module D and Module E. If the customer's request for scope expansion is available, it is accepted to coincide with the surveillance audit.

8.6. Document Refresh Controls

8.6.1. Certificate renewal audit is the audits performed to re-certify the companies when the validity period of the certificate expires.

Companies are warned by the Planning Officer (e-mail or phone) at least 3 months before the expiry date of the certificate and the company is asked for an answer. If the company does not respond or request continuation of the document, the document loses its validity at the end of the validity period.

8.6.2. If the company wants to be certified again after the end of the validity period, the application is treated as certification, not recertification.

8.6.3. If the company requests a certificate renewal, a certificate renewal audit is performed. A new contract is made with the firm in accordance with the pricing rules. Conformity Assessment Application Form is re-filled by the company, the company's old file number is valid. Planning the re-certification 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, a certification decision is taken within 6 months after the end of the certification period and the valid date on the document can be activated after the date of re-certification and the previous certification cycle is based on the validity period, otherwise the process is considered as the first certification.

8.6.4. During the recertification, nonconformities and corrective actions detected in the previous audit are examined. Audit scope, new documents, brand and document usage are checked and action is taken as in surveillance audits. At the end of the audit, the evaluation is made as in the certification audit.

8.7. Other Situations Related to Conformity Assessment Process

8.7.1. Suspension of Inspections / Inspections

Conformity assessment activity can only be stopped if the following conditions are met:

- If it is determined that the requirements or legal sanctions for the product covered by the conformity assessment are not met
- If circumstances during the conformity assessment adversely affect or pose a threat to the health of the engagement team.
- If serious problems are detected in the implementation of the system that hinder the continuation of the conformity assessment and it is understood that follow-up audit is inevitable (In these circumstances, the suspension of conformity assessment is an exceptional case and should be applied as a last resort. In such cases, renewal of the conformity assessment is required).
- If serious problems are encountered or bribes are offered to the relevant personnel in accessing the relevant department or job, product or service records.
- In addition, if the company requests to suspend the conformity assessment due to company-related reasons, it may be suspended provided that the conformity assessment is repeated.

When the team leader decides to stop the conformity assessment, he / she must reach the company representative and explain the reason. During the decision-making process, the team leader should consult with the Technical Regulatory Officer when necessary. The team leader explains the reason for stopping the conformity assessment by calling the company senior management to the meeting. If the certification request of the company is still valid, it is stated that a conformity assessment will be repeated later, provided that the relevant nonconformity is resolved. All details regarding the suspension of conformity assessment should be specified in the report. The relevant report is sent to the company in writing.

8.7.2. Follow-up of Detected Nonconformities

In the Nonconformity Report of the company representative, the required activity to eliminate the nonconformity and the action preventing its repetition is described and requested to be sent to SZUTEST within 10 working days. The team leader checks, verifies and signs that the activity specified in the form is sufficient to eliminate the non-conformity and prevent its repetition, and that it complies with the given deadlines.

However, if it is understood that the activity described by the company is not sufficient to prevent recurrence of the nonconformity, it is returned to the company without being approved by the team leader to be reviewed in the Nonconformity Report.

The maximum period allowed for correction and corrective actions for closing all nonconformities is 60 days at most, regardless of the size of the nonconformity, from the date of writing (it should be ensured that the period to be determined in the certificate renewal audit is before the expiry date of the certificate).

8.7.3. Closing Nonconformities with Tracking

Follow-up is planned for nonconformities that require verification in the field. The appointment and planning process for follow-up is carried out as in the normal conformity assessment process.

Follow-up is carried out as much as possible by the Technical Specialist, who acts as the Team Leader in the first evaluation. If corrective actions are deemed appropriate in follow-up audits, certification phase is initiated in certification and certification renewal audits, and continuity of certification is ensured in surveillance audits.

8.7.4. Unannounced Inspections

SZUTEST can perform unexpected inspections to the manufacturing / assembly area of the product or to the company. During these audits, SZUTEST may, if necessary, conduct or request tests to check the proper functioning of the quality assurance system and product; They must submit the audit report to the firm and, if any, test reports.

In particular, a visit control plan is created by considering the following factors.

- Category of equipment,
- Results of previous inspection visits,
- The need for corrective action,
- Special conditions linked to the approval of the system,
- Significant changes in production organization, policy and technique.

In addition, in the case of complaints involving objective evidence against the company, if a nonconformity is detected in the Market Surveillance and audits carried out by the Ministry, the Technical Regulation Officer may decide to conduct an audit even though he is not in the program.

When assigning the audit team to carry out the audit, the Technical Regulation Officer assigns an audit team that is different from the previous audit team and capable of interpreting the subject of the complaint.

If the firm does not accept the audit, the certificate is suspended with the decision of the Technical Regulation Officer and the company is notified in writing. SZUTEST has stated in the contract signed before the service to the company that it can take this decision. SZUTEST suspends or cancels the certificate, depending on the nature of the unfulfilled conditions, if it determines that the conditions underlying the certificate it has issued as a result of its audit are not available. It provides the necessary information for the purpose of market surveillance and inspection to the relevant Ministry of Industry and Technology and the authorized institution conducting market surveillance and inspection and, if stipulated in the relevant technical regulation, the authorized bodies of the European Union member countries. If requested, it submits information about the evaluation procedures to the commission.

8.7.5 Change controls

These are audits that can be carried out to control changes such as changing the company title, changing or expanding the scope of the company's product, changing the company address and branches, changes in the design, technical file and components of a documented product. These changes should be evaluated by SZUTEST by following the steps below.

1. The customer sends the change to SZUTEST using the FR.30 Certification Change Form.
2. The change is evaluated by the Technical Regulation Officer and the necessary technical or legal documentation is requested from the company.
3. The relevant documents sent by the customer are reviewed by the Technical Regulation Officer and a decision is made whether to conduct a document review or field inspection and is noted on the form. Whether the field inspection is required or not is determined by the Technical Regulation Officer depending on the new scope requested and the content of the scope owned. If it is deemed necessary to inspect the field conditions according to the requested scope, the decision to conduct a field inspection is taken. In addition to document review in scope change and address change audits, field audits are carried out in the required time depending on the scope and production location and are recorded with the relevant audit report. In case of changes in the design, technical file or components of a certified product, the effect of the changes on the basic safety requirements of the regulation is checked. Changes that may cause deviations from the conditions specified in the basic requirements are controlled by performing the necessary tests and examinations in the laboratory. The process is carried out as described in clause 8.3.1 or 8.3.2.
4. If the documents and Audit Report are deemed appropriate by the Technical Regulation Officer, changes are made and noted in the certification change form. The new document is issued and delivered to the company. If the certification change is not deemed appropriate, the company is notified in writing. In document changes, the company's current document validity period does not change.

8.8 Subcontractor Designation Rules

If SZUTEST works with a subcontractor for conformity assessment activities, it chooses a subcontractor according to the following criteria.

- The organization is carrying out the subcontracted service accredited,
- Price policy of the organization regarding the services to be subcontracted,

8.9 Review and Decision

It is carried out according to the PR.ATEX.04 Certificate and Reporting Procedure.

8.10 Reporting and Certification

It is carried out according to PR.ATEX.04 Certificate and Reporting Procedure.

8.11. Remote Control

8.11.1. This article is considered only within the scope of the conformity assessment processes defined in 8.3.

Remote control techniques cannot provide the outputs provided by field control in all cases. For this reason, SZUTEST's priority approach is to carry out inspections on-site.

The period between the dates of subsequent decertification/document renewal and the date of the audit may not exceed 15 months. However, if SZUTEST decides that on-site supervision is not feasible due to extraordinary events and circumstances, it may use the remote supervision technique to achieve the same goal as on-site supervision.

8.11.2. The level of application of remote control 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, if it has already been

certified, the results of the initial certification and supervision.

8.11.3. Remote controls cannot be applied in the first certification audit. However, it can be used as part of the first certification audit if it is deemed necessary. After the termination of extraordinary events and conditions, field inspections are carried out. In case of continuation of extraordinary events and circumstances, the certification process is continued until the end of the situation.

8.11.4. For surveillance audits; 8.11.2 due to extraordinary events and circumstances. according to the article, remote control techniques may be preferred. After the end of the extraordinary events and conditions, field inspections are carried out by the same inspection team.

8.11.5. The audit team, including the opening meeting and closing meeting, must have remote access to the management representative/factory production control officer. Interim meetings can be held when the audit team needs it, by disabling the audited party's access. Each audit team member and audited party officials share audit records electronically. Before the audit, a trial connection should be made and the compliance of the connection conditions of the audited party and the audit team should be confirmed by the parties. Before, during and after the audit, the audited party transmits the documents and records that the audit team needs to review in the audit electronically. These documents and records will be stored electronically on the SZUTEST server for 10 years. Reporting of the audit, findings and practices will be carried out and completed in accordance with articles 8.3, 8.4, 8.5, 8.6, 8.7, 8.9 and 8.10.

8.11.6. In the process of implementing a remote audit, if the audited party cannot continue the processes specific to this audit technique or the audit team cannot perform the remote audit adequately, the remote audit may be repeated depending on SZUTEST's decision, a new remote audit may be performed for the missing parts, or an on-site audit may be performed.

8.12. Temporary alternative extraordinary measures and arrangements for on-site inspections

These temporary alternative extraordinary measures include the following principles and regulations:

Postponement of on-site surveillance inspections for force majeure.

Replacement of on-site inspections with remote inspections using the most advanced Information and Communication Technologies that are appropriate in accordance with information security and data protection legislation.

Off-site evaluation of all relevant and necessary documents / records by SZUTEST.

It should carefully evaluate, document and realize the possibility of taking advantage of temporary alternative extraordinary measures for on-site inspections on a case-by-case basis, using a risk-based approach. In particular, the risk assessment, which determines the possibility of using these alternative measures, should take into account the experience gained with the organization to be certified. For example, with regard to production/operational control for organizations with a large number and/or a history of critical non-compliance, taking such temporary measures may have an impact on the organization's compliance. However, as a temporary measure in these cases, an alternative measure, such as an on-site inspection, should be applied after the travel restrictions have been lifted.

In order to evaluate which alternative extraordinary measure is the most appropriate, SZUTEST should evaluate the manufacturer's status and files related to its activities related to this audit, for example, the area to be audited, the quality management system, and the level of compliance with previous audits. First of all, you should contact the organization and be notified by the Planning Coordinator FR.ATEX. With Form 50, you should evaluate the following information. It must be approved by the Unit Manager.

Does the organization have a history of numerous and/or critical nonconformities or critical weaknesses in the previous audit report, or critical processes that are recommended to be examined in the next audit?

Has a "Follow-up or hanger audit" been performed in the recent history of the organization?

When will the organization be able to function normally?

When can the organization ship or perform the products or service defined under the current certification?

Will the organization need to use alternative production and/or distribution sites? If so, are they currently covered by the current document or do they need to be evaluated?

Does the certified organization have a disaster recovery plan or an emergency response plan, has the certified organization implemented this plan and is it effective?

Will some of the transactions and/or services performed or products sent be subcontracted to other organizations? So, how will the activities of other organizations be checked by the certified organization?

To what extent has the functioning of the management system been affected?

Has the certified organization conducted an impact assessment?

Defining a check that the organization has the necessary infrastructure to support the use of the proposed ICT.

In cases where postponement cannot be justified, SZUTEST should be evaluated by the Planning Coordinator and the Department Manager which alternative extraordinary measure should be taken (Eg. Remote control; off-site document review; such as conference calls with relevant organization personnel).

For remote inspections, both SZUTEST and the manufacturer are required to have and install the necessary information and communication technologies or tools. (e.g. document-sharing web conferences, control of production lines). The confidentiality of intellectual property rights must be protected. SZUTEST must clearly document and communicate such requirements for its audits with its auditors, including the necessary data protection and cybersecurity measures, documents that must be shared before and within these audits. The technological ability of the organization to ensure that such an audit can be carried out must be verified by the Planning Coordinator before the audit.

The Competent Authorities may request to observe / testify to such remote inspections through existing and created information and communication technologies or tools.

When creating the audit plan, SZUTEST must set the time for reviewing the fields in the audit plan, together with the overall duration of the audit, in coordination with the manufacturer for the effective use of this alternative. The audit plan should also clearly indicate which alternative extraordinary measures will be used and what will be carried out remotely. When editing audit reports, SZUTEST should make it clear that the audit is being conducted remotely, and it should also specify the method(s) used for these audits.

Remote surveillance audits should cover all surveillance tasks that can be verified remotely, including on-site examination of all documents that would normally be evaluated on-site.

After such an alternative extraordinary measure, SZUTEST should review and adjust the audit program for each manufacturer.

8.12.1 I. Surveillance Audits

Normally, the first surveillance audit date to be carried out after the first certification is planned based on the certification decision date, not exceeding 12 months.

If it is not possible to carry out a surveillance audit during the normal period due to the Covid 19 pandemic, SZUTEST must first conduct a remote audit before the 12-month period is completed. 1. If remote control is not possible. Supervision can be extended for 6 months, that is, it can be carried out 18 months after the last day of the first certification date. Evidence of this fact should be recorded by SZUTEST.

Otherwise, the certificate should be suspended or reduced in scope according to the PR.ATEX.04 Certification Procedure.

There may be certain situations in which SZUTEST may justify adjusting the timing of the next surveillance audit. If an organization needs to completely close for a limited time (less than 6 months,

SZUTEST may postpone an audit scheduled for closure until the organization resumes its activities. The organization must inform SZUTEST when it becomes operational so that SZUTEST can conduct the audit immediately. The organization should be informed about this.

8.12.2 II. Surveillance Audits

A surveillance audit scheduled for 2021 may be postponed to any date in 2021 due to the Covid 19 pandemic (the most recent audit date is the end of 2021). II. The supervision audit is carried out by remote control, it is decided to maintain the document and a field audit is carried out within the calendar year.

8.12.3 Re-Certification Audit

SZUTEST must first perform and complete the recertification audit before the end of the previous certification period. If this is not possible due to the Covid 19 epidemic situation mentioned above, a remote audit should be carried out first in accordance with current internal regulations in order to conduct and schedule a re-audit. This remote audit can cover no more than 50% of the calculated on-site audit time, and the management review should include an audit of the basic standard requirements, such as internal audits, partial checks for corrective and preventive actions (especially for non-compliance and deviations from previous audits). After this remote inspection, an on-site inspection (field inspection) is carried out by SZUTEST to prove the suitability of the certified product. In case of a positive certification decision, a new certificate valid for another three years may be issued (the document is issued for 6 months). A field inspection should be carried out by SZUTEST within 6 months after the certification date.

Normally, in order to prevent document loss, a recertification audit should be completed and a recertification decision should be made before the expiration date. However, provided that sufficient evidence is collected as above, an extension of the document for a period of time may be considered to provide assurance that the documented management system is effective. This period normally cannot exceed 6 months after the original expiration date.

Recertification should be carried out within this allowed long period of time. Otherwise, a new initial audit should be carried out. The expiration of the renewed document must be based on the original recertification cycle.

8.12.4 Informing the Competent Authority

All deviations from the certification /Conformity assessment program must be justified, documented and submitted to the Competent Authorities on request.

8.12.5 Mandatory Control Before Switching to Remote Control

Remote control compliance: It should be checked that the standard and/or the relevant article are eligible/ authorized for remote control.

Past experience of the organization: It should be checked that the results of previous inspections, a recent reorganization or a long-standing on-site audit have not disqualified the client for a remote audit.

Technical feasibility: Given the availability of the necessary ICT infrastructure, it should be checked whether customers are eligible for remote control.

It should be checked whether the connection has been tested before inspection.

Audit Team Preparation: Auditors or technical experts who will participate in a remote audit should have the ability to understand and use the information and communication technologies used to obtain information and communication technologies when using ICT. They should have knowledge about ICT and its impact on the validity and limitations of information collected using this methodology. They should be aware of the risks, opportunities of the ICT used and its impact on the validity and impartiality of the information collected.

Remote control time: It is checked whether the planned time corresponds to the maximum allowable time, given the scope of the audit. If the ICT is used for audit/evaluation purposes, it should be taken into account when planning the total audit/evaluation period, as October planning may be required, which may affect the audit/evaluation period.

8.12.6 Considerations While Performing the Audit

The planned approach is approved by the auditor in the audit planning, and then at the opening meeting.

During a remote audit, the security and confidentiality of information transmitted electronically or electronically is of particular importance when using ICT for audit/evaluation purposes.

During the audit, it may not be possible to record dec/video recordings of the entire audit process. However, in addition to the minimum opening and closing meetings, in other cases that the audit team deems appropriate, dec/video recordings of the audit should be recorded.

Simultaneous use of applications located on the auditor's computer that are not suitable for ICT should not be allowed.

It is worth noting that there are security/privacy tools, that is, customization screens, headphones, etc. it is highly recommended to use it and use a separate room.

Your teams, Skype, etc. when using tools, it is preferable to use a customer invitation.

Audit report: The Audit Report should clearly define to what extent an ICT is used to perform the audit and the effectiveness of the ICT in

achieving the audit goals.

The Audit Report is filled in with the records of people who participated in the remote audit.

During the implementation of the remote audit, all necessary measures should be taken to ensure the confidentiality of the audit of the organization and the audit team.

All necessary audit documents must be completed in accordance with the relevant procedures.

8.12.7 ICT Methods that Can be Applied in Audits

Information and communication technologies are the use of technology to collect, store, receive, 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.

The ICT can be suitable for both local and remote control/evaluation.

Examples of the use of ICT during inspections/evaluations may include, but are not limited to:

- Meetings; through teleconferencing facilities, including audio, video and data sharing
- Inspection/evaluation of documents and records via simultaneous (real-time) or asynchronous (if any) remote access
- Recording information and evidence with still video, video or audio recordings
- Providing audio / visual access to remote or potentially dangerous places

For audits, the Audit Team is required to use reliable communication tools such as Skype, Snagit, Google, Microsoft, approved by SZUTEST.

Communication tools that are not approved by SZUTEST cannot be used.

8.12.8 Prohibited Practices

-Conducting remote control in public places (Eg. Train, cafe, etc.).

-Conducting a remote audit in a room with other people who are not part of the audit team.

-It is forbidden to store the records obtained during the audit on personal computers, except for computers registered with SZUTEST.

8.12.9 Decisions Taken on Certification

Remote audits for the purpose of recertification should cover all mandatory recertification tasks that can be verified remotely. After a successful remote audit, SZUTEST may re-issue the certificate, provided that these evaluations are followed by an on-site verification audit at the next appropriate opportunity to verify its items that cannot be evaluated remotely.

The planned timetable for the on-site verification audit should be justified by SZUTEST.

At the request of SZUTEST, the organization can provide SZUTEST with the necessary records on a permanent or regular basis. If the recertification remote audit fails, the certificate should be suspended or expired according to the PR.ATEX.04 Certification Procedure.