MEASURING INSTRUMENTS REGULATION CERTIFICATION PROCEDURE
TS EN 1706517065

1. PURPOSE AND SCOPE

This procedure aims to regulate the procedures and principles regarding the inspection and certification stages of the "Measuring Instruments" specified in the Conformity Assessment Manual and covers the examination of the quality modules shown in Table: 1 below.

2. RESOURCES UTILIZED

- **2014/32/ EU Measuring instruments regulation**
- **Communiqué of the Ministry of Industry and Technology dated September 24, 2019 and numbered 30898**

3. DEFINITIONS

Pre-audit: For Module D certification, the review and examination of the establishment, implementation and effectiveness of the quality management system by sampling method in a lesser time frame. The pre-audit is carried out by an auditor.

Module B audit/review: It is the audit carried out by examining the technical file of the design of the measuring instruments and, if necessary (if the product is to be inspected / tested and observed in the customer's laboratory), by performing production control..

Module D audit: Quality management system for measuring instruments and product quality and routine inspections / tests are carried out, controlled and production and surveillance are carried out..

Phase 1: It is the level where the QMS and product quality are pre-audited.

Phase 2: It is the process in which technical data is examined, routine inspections/experiments are controlled, and production is supervised and controlled.

Module F audit: It is an audit in which the adequacy of the laboratory is checked and the experiments are observed and evaluated by taking samples.

Follow-up audit: In Module D certification, an on-site audit of the organization to review and examine whether nonconformities related to the establishment, implementation and effectiveness of the management system have been eliminated.

Surveillance audit: After the Module D Certificate is issued, at least 1 (one) audit per year to review the implementation and effectiveness of the quality management system by sampling method according to the mutually predetermined standard in certain parts of the company.

Recertification audit: For the renewal of the certificate issued, the audit carried out in the company according to the mutually predetermined standard in order to review the implementation and effectiveness of the system by sampling method, covering the entire management system.

Scope expansion audit: Audit conducted to examine the implementation and effectiveness of the management system on the previously out-of-scope departments and/or activities of the company.

Visitation control system: A visit aimed at the controls made by the manufacturer on the basis of the control system implemented in order to determine whether the quality system is operating correctly.

Nonconformities: The absence of one or more of the requirements of the management system or whether the product is produced in accordance with the standard, the absence of one or more of the requirements, or the failure to implement or maintain the implementation of these item / items, or a situation that may lead to the adequacy of the application in the company according to the available objective evidence..

Situations that lead to the following situations are also considered non-conformities.

- Deterioration of the efficiency of the system,
- Limiting the ability to keep processes under control (based on available evidence and experience),
- Leading to the shipment of non-conforming product,

Technical Expert: Personnel working full-time within Sastek A.Ş. who carry out the planned examinations and / or audits within the scope of the conformity assessment activities to be carried out by the notified body in accordance with the Measuring Instruments Regulation and evaluate the results of the examination and / or audit, present and report to the technical regulation officer.

External Technical Expert: Personnel appointed by Sastek A.Ş., determined according to their competence, performing the planned examinations and / or audits within the scope of the conformity assessment activities to be carried out by the notified body in accordance with the Measuring Instruments Regulation, and evaluating the results of the examination and / or audit, presenting and reporting to the technical regulation officer.

3. RESPONSIBILITY

- **Program and activities officer:** Providing information about the application, receiving, registering, checking the application, forwarding the application to the control officer,

- **Product certification manager**
  Appointment of audit team, supervision and control of checking the application, appointment of lead auditor, auditor technical expert, planning of certification and audit, reviewing the conformity of the audit result and forwarding it to the Technical Regulatory Officer for review and decision making for B, F modules, forwarding the D module certification to the Certification Committee for decision making, supervision and control of the review of the review/audit; issuance, continuation, suspension, cancellation, scope extension/reduction of the certificate ,

- **Auditor/Technical Expert/External Technical Expert**
  Reviewing the file of all modules, conducting and evaluating the audit/inspection, reporting nonconformities, preparing the audit report, reviewing the documents of the entire file of the product and reporting the results, monitoring the implementation of the system,

  In addition, the lead auditor is responsible for the following.
  Advising on the coordination of audit planning, communication for the audit, coordination and supervision of auditors, preparation of reports, reporting and timely submission of audit results (coordinating with auditors if necessary), preparation of nonconformity reports, follow-up audit, termination of audit and decision on scope,

- **Technical Arrangement Officer**
  To evaluate and review the Module B, D and F examination/audit activities carried out, to decide on the issuance, continuation, suspension, cancellation, extension/reduction of the scope of Module B and F certificates.

4. APPLICATION

4.1 General

4.1.1 The audit quality modules applied by Sastek in the certification of measuring instruments are shown in Table: 1.

Table 1: 2014/32/EU Regulation on measuring instruments (OG. dated 29.06.2016 and numbered 29757)

Module	**Description**
Module B	EU Type product approval; conformity of the product to the requirements of the relevant regulation
Module D	Declaration of Conformity to the Type Based on Quality Assurance Regarding the Manufacturing Process

Module F	Declaration of conformity to type based on product verification

4.1.2 According to the "Regulation on Measuring Instruments" published in the Official Gazette dated 29.06.2016 and numbered 29757; the references of the modules according to their categories are established as shown below.

Quality module references for measuring instruments:

- Module D
- Module B+D or Module B+F

4.2 Application

4.2.1 For the conformity assessment application to Sastek, information can be obtained by calling 0312 385 35 34, the application can be obtained from www.sastek.com.tr web page. The application is received, recorded and forwarded to the control officer by the program and activities officer.

4.2.2 The control officer reviews the application and its annexes with the application control form under the supervision and control of the product certification manager. Control (Review of the Application) is carried out in the context of company information, the appropriateness of the requested documents and their content, resource adequacy / need neutrality violation status, whether there is a need for production control in Module B and elimination of deficiencies, if any.

4.2.3 If any, the deficiencies are notified to the applicant by e-mail or telephone and the application is forwarded to the relevant person and requested to be corrected.

4.2.4 If the application review, application control is appropriate, the Product Certification Offer/contract is prepared by the Accounting unit. For this;

- (If necessary) The experiments to be performed, the laboratory where the experiments will be performed,
- Certification program, fees and payments, rights and obligations of Sastek and the customer regarding the use of documents and logos,
- Legal requirements, customer terms and changes,
- And other contractual matters are evaluated, the proposal is prepared, approved by the General Manager and sent to the customer.
- In the product certification Offer/Contract (ÜDD.11), an article may be added or removed as a result of joint negotiation with the customer company.

4.2.5 The offer is followed up by the product certification unit, the issues related to the offer that the customer wants to be changed are evaluated, the offer is revised in the context of those deemed appropriate, its approval is checked and verified, the offer gains contract status with the stamp and signature of the customer, a copy is sent to the customer.

4.3 Traceability of procedure documents

4.3.1 Codes for the traceability of the documents related to the Measuring Instruments Regulation, Quality Module Certification Procedure documents and documents related to other regulations within the scope are defined in the Document Control Procedure.

Related documents:

- **Procedure for control of documents (ÜPR.07)**

- **Customer Privacy Statement and Commitment (ÜDD.17)**
- **Product Certification Offer/Contract (ÜDD.11)**

4.4 Audit periods

4.4.1 In the audits to be carried out by Sastek within the scope of the 2014/32/EU Measuring instruments regulation Module D certification, the relevant instruction has been prepared and implemented based on the guide for calculating the audit times (person / day) for TÜRKAK R10.09 Accreditation audits in determining the audit times..

Related documents:

- **Inspection periods, fees and payment instructions (ÜTL.06)**

4.5 Planning the certification (For Mod. B, D and F)

4.5.1 Product Certification manager plans the certification process together with the Program and Activities Officer.

By including;

- Product name, type, class, type, etc.,
- Product related standards/criteria, module/system and scope,
- Which examinations and tests will be carried out in which laboratory for certification,
- Routine inspections and tests and environmental conditions,
- What are the legal requirements for the product,
- Legal requirements for the production facility,
- Machinery, equipment, hardware, etc. that must be included in the production equipment according to legal and standard requirements,
- Requirements for quality management system,
- Adequacy of quality control facilities,
- The conditions of interim controls, the amount of samples to be taken and special conditions, if any,
- Information on the certification method,
- Devices subject to calibration; this plan is prepared.

***ÜFR.066 Measuring Instruments Certification Plan**

4.5.2 For the first stage of the Module D certification audit, a pre-audit (Assessment visit) is planned and carried out at the manufacturer's site. In the pre-audit, the establishment, implementation and effectiveness of the quality management system are reviewed and examined by sampling method. **(Module D Phase 1 Evaluation Report ÜFR.013)**

4.5.3 If Stage 1 of Module D is completed and the assessment is found to be appropriate, a Stage 2 audit is scheduled or the audit is continued. Both phases can be done at the same time. When forming the audit team for Module D, it is ensured that at least one member has quality management system experience. This may be a Lead auditor or auditor appointed according to TS EN ISO 17021. Product Certification manager; determines the appropriate auditor team, audit date-duration, obtains customer approval by phone or e-mail, evaluates customer requests, if any. Appoints auditors, prepares the audit plan in coordination with the lead auditor or auditor. The product certification manager prepares the audit file and obtains a commitment of confidentiality and impartiality from the client.

4.5.5 AUDITS:

. Audits are carried out by performing the following sequential activities according to their modules.

a- MODULE B REVIEW / AUDIT:

* Module B is a module where technical information is examined, so it is done at the desk at Sastek. If the customer will perform the inspection and tests in its own laboratory, the company is inspected at the company for the control of production and tests.

MODULE B (EU TYPE EXAMINATION) REQUIREMENTS:

EU Type Examination is a conformity assessment in which a notified body examines the technical design of a measuring instrument and declares that the technical design complies with the requirements of the Measuring Instruments Regulation.

- EU Type Examination can be carried out by any of the following methods;

1. Examination of a sample of a complete measuring instrument to represent the prescribed form of manufacture **(type of production)**

2. Examination of the technical documents and supporting evidence, assessment of the adequacy of the current technical design of the measuring instrument and examination of samples taken from one or more important parts of the measuring instrument representative of the envisaged form of manufacture **(combination of manufacturing type and design type)**

3. Assessment of the adequacy of the technical design of the measuring instrument by examination of the technical file and supporting evidence, without examination of any samples **(design type)**

The notified body takes decisions on the appropriate methods and samples it deems necessary. The manufacturer of the measuring instrument applies for EU Type (Module B) examination to a single notified body of his choice. Written declaration from the manufacturer that the measuring instrument has not applied to another notified body for EU Type examination.

The manufacturer must submit its name and address in the application of the measuring instrument in question; if the application is made by its authorized representative, the name and address of the representative, the technical file of the measuring instrument to the Notified Body. Samples representative of the intended production run are requested from the manufacturer. More samples may be required by the notified body in order to carry out the test program. Supporting evidence that the solution for technical design is adequate (in particular the documents used in cases where the relevant harmonized European Standards and / or norm documents are not fully implemented) is provided by the manufacturer to the Notified Body..

The Notified Body examines the technical file and supporting evidence to assess whether the technical design of the measuring instrument is adequate, verifies whether the sample or samples are manufactured in accordance with the technical file, identifies elements designed in accordance with the relevant provisions of the relevant harmonized European standards and/or norm documents, as well as elements prepared in accordance with other technical specifications.

The manufacturer of the measuring instrument shall carry out or have carried out the appropriate examinations and tests specified in the relevant harmonized European standards and norm documents.

The notified body shall issue an evaluation report in which the results of the measuring instrument are recorded and an EU type examination certificate to be issued to the manufacturer if the measuring instrument meets the requirements of the Measuring Instruments Regulation. This certificate has a validity of 10 (ten) years and is renewed every ten years.

- **The EU type examination certificate is valid with Annex (Annex Final Protocol). The Annex contains the following information;**

- Metrological characteristics of the measuring instrument type
- Necessary precautions to ensure the integrity of the measuring instrument (stamping, software identification, etc.)
- Identification of the measuring instrument and information on other elements necessary to verify the conformity of its external appearance to the type
- Where appropriate, the detailed information necessary to verify the characteristics of the manufactured measuring instruments (test reports, technical information, etc.)
- If a sub-assembly device is used, all necessary information to ensure compatibility with other sub-assemblies or measuring instruments.

The notified body refuses to issue the EU Type examination certificate if the type of measuring instrument in question does not meet the requirements of the Measuring Instruments Regulation and notifies the applicant in writing, explaining in detail the reasons for this refusal.

The manufacturer is obliged to notify the Notified Body of any changes that may affect the conformity of the approved measuring instrument with the essential requirements or the conditions for the validity of the EU Type Examination certificate. Such changes are revised in addition to the original EU Type certificate.

The Notified Body and the manufacturer shall keep the EU Type examination certificate and its annexes for 10 (ten) years. Keep the EU Type Examination documents and/or annexes issued or withdrawn ready for submission to the Ministry of Industry. In addition, the Commission, Member States and other notified bodies may obtain copies of the EU Type Examination documents and/or their annexes upon request.

- **Technical File Content in EU Type Examination:**

The technical file shall be organized in such a way as to make the design, manufacture and operation of a measuring instrument comprehensible and to enable the assessment of its compliance with the requirements of the Measuring Instruments Regulation. The technical file should be detailed in a way that will ensure the following;

1. Definition of metrological characteristics
2. Reproducibility of the metrological performance of the manufactured measuring instrument when correctly adjusted using the appropriate method
3. Accuracy of the measuring instrument
4. General description of the measuring instrument
5. Design and manufacturing drawings, blueprints of elements such as components, sub-assembly devices and circuits.
6. Manufacturing processes to ensure proper production.
7. Where applicable, a description of electronic devices, including drawings, diagrams, logic flow diagrams and general software information to explain their features and operation.

8. Descriptions and explanations necessary for the understanding of points (5), (6) and (7), including the operation of the measuring instrument.
9. List of harmonized European standards and / or norm documents referred to for the measuring instrument, references to which are published in the Official Journal of the European Union, fully or partially applied.
10. Descriptions of the solutions adopted to meet the essential requirements, including a list of other relevant technical specifications applicable where the harmonized European standards and/or norm documents referred to do not apply.
11. Results of design calculations and investigations.
12. If necessary, the relevant test results showing that the type and/or measuring instruments comply with the requirements of the Measuring Instruments Regulation and the durability characteristics of gas, water, heat and liquid meters other than water under the declared defined operating conditions and specified environmental disturbances.
13. EU type examination certificates or EU design examination certificates for measuring instruments containing the same parts as those in the design.
14. The manufacturer specifies the places where the seals and markings are applied.
15. The manufacturer shall, where necessary, indicate the requirements for the suitability of the measuring instrument for interfaces and sub-assemblies.

*** If Module B Review will be performed at the Customer Company Address:**

1. The application is received, reviewed, checked and, if appropriate, the offer is submitted, the offer replaces the contract when signed.

- Measuring Instruments Regulation Module B Application Form (ÜFR.001)
- Module B Application Control Form (ÜFR.004)
- Product Certification Offer-Contract (ÜDD.11)

2. From the Technical Expert Competency Table (ÜDD.27), the Technical Expert with the competence appropriate to the product to be certified is assigned. (ÜFR.040)

- Since the quality system of production will not be examined in Module B, no Lead Auditor or auditor will be appointed.

The product certification manager prepares the audit plan in coordination with the Technical Expert or External Technical Expert. (ÜFR.007) Module B inspection will be carried out at the customer address.

- Since technical issues will be considered, 1 Technical Expert or 1 External Technical Expert is sufficient. If necessary (e.g. if the product has both mechanical and electronic components), Technical Experts with competence in a machine and an electronic department can be appointed)

3. Product Certification Manager receives customer confirmation for audit date, duration and Technical Expert by phone or e-mail. The assigned Technical Expert goes to the company address on the planned day and time.

3.1. Opening Meeting is held. (ÜFR.041)

3.2. Technical file of the product is examined and evaluated. (ÜFR.014)

3.3. Final control tests of the product in the customer laboratory are carried out under the supervision of the Technical Expert (ÜFR.018)

3.4. In case of non-conformity, UFR.063 is used. The company is given time to eliminate non-conformities (maximum 90 days).

3.5. After all reports are filled in properly, a Closing meeting is held with the company officials. (ÜFR.041)

3.6. If there is a nonconformity in the inspection and test laboratory evaluation or test results, the audit is stopped and a closing meeting is held. (ÜFR.041)

3.7. After the non-conformity or non-conformities found in other subjects are closed, the Technical Expert prepares the Module B Review Result Notification Report (ÜFR.020) and the Final Protocol is prepared. Together with the reports, the prepared and signed Final Protocol and the Technical File of the Product are delivered to the Technical Regulatory Officer..

3.8. As a result of the audit, technical files and reports, the company's file is reviewed by the Technical Regulatory Officer (ÜFR.011) In case of possible deficiencies in the reviewed files and reports, the Technical Regulatory Officer informs the relevant person and the deficiencies are eliminated within a maximum of 1 week.

3.9. The Technical Regulatory Officer decides to issue or not issue a certificate after review. (ÜFR.011)

3.10. If the Module B certification decision will be made with a Technical Expert working full time within Sastek A.Ş. for the product:

3.10.1. The certification process is initiated by the Technical Regulatory Officer through the Ontek portal of the Ministry of Industry and Technology. The Technical Regulatory Officer logs in to the Ontek portal with ID number and E-Government password. Ontek marks Module B (EU Type Approval) from the New Certification section of the portal, enters the company's information and product information, and sends it to the Technical Expert who makes the evaluation via the portal. The relevant technical expert approves the certification on Ontek by logging in with TR Identity Number and E-Government password. After the approval is ticked; uploads the Module B Review and Decision Making Form (ÜFR.011), the test reports of the product, the final protocol to the portal and sends it back to the Technical Regulatory Officer.

The Technical Regulatory Officer enters the Ontek portal again with his e-government password, assigns a Module B Certificate number with the Certify option, sets the validity date as 10 (Ten) years and completes the certification process with the Certify option. The QR code to be added to the certificate is created. The QR Code is forwarded to the Product Certification Manager and the Module B certificate of the product is prepared in line with the information in the QR code.

-ÜUB.01 EU Type Product Approval Certificate

3.11. If the Module B certification decision is to be made with the External Technical Expert for the product:

3.11.1. The certification process is initiated by the Technical Regulatory Officer through the Ontek portal of the Ministry of Industry and Technology. The Technical Regulatory Officer logs in to the Ontek portal with TR Identity Number and E-Government password. Ontek marks Module B (EU Type Approval) from the Certification with External Expert section of the portal, marks the External Technical Expert who performs the evaluation by entering the company's information and product information. Module B Review and Decision Making Form (ÜFR.011), product test reports, Final protocol are uploaded to the portal in the document addition section. The Technical Regulatory Officer assigns a Module B Certificate number, sets the validity date as 10 (Ten) years and completes the certification process with the Certify option. The QR code to be added to the certificate is created. The QR Code is forwarded to the Product Certification Manager and the B Module certificate of the product is prepared in line with the information in the QR code.

-ÜUB.01 EU Type Product Approval Certificate

*** If Module B Review will be conducted at Sastek A.Ş. at the desk:**

- If Sastek is requested to perform the type tests in the technical file content; Sastek TS EN ISO / IEC 17025 system is considered as an internal customer and the activity is carried out with the Test request form in this system. Test request format is defined in TS EN ISO 17025 System.

1. The application is received, reviewed, checked and, if appropriate, the offer is submitted, the offer replaces the contract when signed.

- Measuring Instruments Regulation Module B Application Form (ÜFR.001)
- Module B Application Control Form (ÜFR.004)

- Product Certification Offer-Contract (ÜDD.11)

2. From the Technical Expert Competency Table (ÜDD.27), the Technical Expert with the competence appropriate to the product to be certified is assigned. (ÜFR.040)

- No Lead Auditor or auditor is appointed in Module B as the quality system of the production will not be considered. The product certification manager prepares the audit plan by confirming with the Technical Expert or External Technical Expert. (ÜFR.007) Module B inspection will be carried out at the desk in the Sastek office It is stated in the audit plan.
- Since technical issues will be considered, 1 Technical Expert or 1 External Technical Expert is sufficient. If necessary (e.g. if the product has both mechanical and electronic components, Technical Experts with competence in a machine and an electronic department can be appointed)

3. The External Technical Expert arrives at the Sastek office on the scheduled date and time according to the Audit Plan. If the review is to be carried out with a full-time Technical Expert, the Technical Expert makes the assessment in accordance with the audit plan.

3.1. Technical file of the product is examined and evaluated. (ÜFR.014) All documents and test reports prepared by the company for the product are checked.

3.2. n case of non-conformity, ÜFR.063 is used. The company is given time to eliminate nonconformities. (Maximum 90 days) Nonconformities are communicated to the customer company via e-mail.

3.3. After the nonconformity or nonconformities are closed, the Technical Expert prepares the Module B Inspection Result Notification Report (ÜFR.020) and the Final Protocol is prepared. Together with the reports, the prepared and signed Final Protocol and the Technical File of the Product are delivered to the Technical Regulatory Officer.

3.4. As a result of the examination, technical files and reports and the company's file are reviewed by the Technical Regulatory Officer (ÜFR.011) In case of deficiencies in the reviewed files and reports, the Technical Regulatory Officer informs the relevant person and the deficiencies are eliminated within a maximum of 1 week.

3.5. The Technical Regulatory Officer decides to issue or not issue a certificate after review. (ÜFR.011)

3.6. If Module B certification is to be carried out with a Technical Expert appointed within Sastek A.Ş. for the product for which a certification decision has been taken: 3.11.1. is repeated.

3.7. If the Module B certification decision is to be made with the External Technical Expert for the product : 3.12.1. is repeated.

b- MODULE D (Declaration of Conformity to the Type Based on Quality Assurance Regarding the Manufacturing Process)

D MODULE REQUIREMENTS:

The Declaration of Conformity to the Type Based on Quality Assurance of the Manufacturing Process (Module D) is part of the conformity assessment process in which the manufacturer declares that it is solely the manufacturer's responsibility to ensure that the relevant measuring instrument conforms to the type defined in the EU Type examination certificate and meets the requirements of the Measuring Instruments Regulation applicable to such instruments.

The manufacturer applies to a single notified body of his choice for the evaluation of the quality system in relation to the measuring instruments in question. In this application;

- Name and address of the manufacturer; if the application is made by its authorized representative, the name and address of this representative,
- Written declaration that the same application has not been made to another notified body,
- All information on the prescribed measuring instrument category,
- Documents related to quality system,
- A copy of the technical file and the EU type examination certificate of the approved type

The quality system ensures that the measuring instrument conforms to the type defined in the EU Type-examination certificate and to the requirements set out in the Measuring Instruments Regulation. The elements, requirements and provisions implemented by the manufacturer shall be documented systematically and regularly in writing in the form of policies, procedures and instructions. In particular, these documents shall include;

- Quality goals, organizational structure of the organization and management's responsibilities and authorities related to product quality
- Manufacturing, quality control and quality assurance techniques, processes and systematic activities to be used
- Inspections and tests to be applied before, during and after the manufacture of the measuring instrument and their application frequencies,
- Audit reports, test and calibration data, records on qualifications of relevant personnel
- Records to ensure that the measuring instrument achieves the required product quality and that the quality system is functioning effectively

The notified body assesses the quality system to determine whether the requirements of the above clauses for Module D certification are met by the manufacturer. The elements of the quality system that comply with the equivalent specifications of the relevant harmonized European Standards are expected to comply with these requirements.

In the Module D audit, there is at least 1 (one) person whose competence in the relevant measuring instrument has been proven and appointed. Audit and evaluation is carried out at the manufacturer's production facility.

The audit team reviews the technical file of the measuring instrument to verify whether the manufacturer has the requirements under the Measuring Instruments regulation. Decisions taken (inspection results and reasoned assessment decision) are notified to the manufacturer.

The manufacturer is obliged to notify the Notified Body of any changes to the quality system. The Notified Body assesses whether the changed quality system meets the requirements and notifies the manufacturer of its decisions on this matter.

The manufacturer allows the Notified Body to enter the manufacturing, inspection, testing and storage locations for the purpose of inspection during the inspection and must provide the following information to the Notified Body;

- Documents related to quality system
- Audit reports, test and calibration data, records on qualifications of relevant personnel, etc.

The Notified Body conducts periodic audits to ensure that the manufacturer maintains and implements the quality system. In addition, the Notified Body may make unexpected visits to the manufacturer in order to verify whether the quality system is functioning properly, and if necessary, applies or applies tests to the product during these visits.

The manufacturer affixes the CE marking, additional metrological markings and the number of the Notified Body (Sastek Notified Body No: 2759) to each measuring instrument conforming to the type defined in the EU Type examination certificate that meets the requirements specified in the Measuring Instruments Regulation. In Module D audits, this information is also checked on the product.

The Notified Body and the manufacturer shall keep the EU Type examination certificate and its annexes for 10 (ten) years. Keep the EU Type Examination documents and/or annexes issued or withdrawn ready for submission to the Ministry of Industry.

MODULE D (Declaration of Conformity to Type Based on Quality Assurance Regarding the Manufacturing Process) Certification

1. The application is received, reviewed, checked and, if appropriate, the offer is submitted, the offer replaces the contract when signed.

- Measuring Instruments Regulation Module B Application Form (ÜFR.002)
- Module D Application Control Form (ÜFR.005)
- Product Certification Offer-Contract (ÜDD.11)

2. According to the Audit Periods Wage and Payment Instruction, the number of audit team is determined according to the effective number of employees working in the client company. Lead auditor - The appropriate auditor or lead auditor is selected from the Auditor List (UDD.29) and appointed (ÜFR.040). The Technical Expert with the appropriate competence for the product to be certified is selected from the Technical Expert Competency Table (ÜDD.27) and assigned. (ÜFR.040)

- At least 1 Technical Expert or at least 1 External Technical Expert must be assigned with the competence appropriate to the product to be certified.
- The audit team should not have any commercial activities (including consultancy) with the company to be audited for the last two years and should not have the risks identified in the conflict of interest risk analysis.

3. The product certification manager prepares the audit plan in coordination with the lead auditor or auditor. (ÜFR.008) Depending on the number of employees of the client effective company, there may not be a lead auditor, in which case an auditor is appointed and planning is done with the auditor.
- Planning is made for each auditor to audit 8 hours per day.

4. Product Certification Manager receives customer confirmation of audit date and duration and audit team by phone or email. On the planned day and time, the audit team assigned to the company address goes.
- Transportation, accommodation, etc. are carried out by the Accounting Officer under the coordination of the Product Certification Manager.

4.1. Opening Meeting is held. (ÜFR.041)

4.2. The lead auditor or auditor uses the Stage 1 Assessment Report for Module D (ÜFR.013). If there is a major nonconformity of critical importance affecting product conformity, the Stage 2 audit is not proceeded and a closing meeting is held. For minor nonconformities, the necessary reporting is made and the Stage 2 audit is started and the Stage 2 audit is carried out using the Module D QMS inspection Report. (ÜFR.016).

If the customer company has TS EN ISO 17021 certification from a company with International TS EN ISO 9001 Accreditation (Türkak or Foreign accreditation), ÜFR.016 is not used.

4.3. The Technical Expert or External Technical Expert examines the technical issues related to the product and fills out the report accordingly. (ÜFR.017)

4.4. Lead auditor/auditor or Technical Expert Production Supervision and Control Production control is performed using the Common Questionnaire. (ÜFR.015)

4.5. Final control tests of the product in the customer laboratory are carried out under the supervision of the Technical Expert (ÜFR.018) A report in the company's own format can be used for these final control tests. If a report in customer format is to be used, the signature and date of the person performing the test are required.

4.6. In case of non-conformity, UFR.063 is used. The company is given time to eliminate non-conformities (maximum 90 days)

4.7. After all reports are filled in properly, a Closing meeting is held with the company officials. (ÜFR.041)

4.8. After the nonconformity or nonconformities found are closed, Module D Audit Result Notification Report is issued by the lead auditor or auditor (ÜFR.019). Annex-1 (Annex) of the Product is prepared by the Technical Expert and signed by the General Manager. Together with the reports, prepared and signed Annex-1 The entire inspection file of the product is delivered to the Technical Regulatory Officer.

4.9. As a result of the audit, technical files and reports, the company's file is reviewed by the Technical Regulatory Officer (ÜFR.010) In case of deficiencies in the reviewed files and reports, the Technical Regulatory Officer informs the relevant person and the deficiencies are eliminated within a maximum of 1 week.

4.10. After conducting the review, the Technical Regulatory Officer submits the company file to the Product Certification Manager for forwarding to the Certification Committee.

4.11. Certification Committee; It convenes by informing the Product Certification Manager, examines the company file, decides on the issuance, continuation, suspension, cancellation, expansion / reduction of the scope of the file reviewed by the Technical Regulation Officer.

a. If the Module D certification decision is to be made with a Technical Expert working full time within Sastek A.Ş. for the product:

4.11.1. The certification process is started by the Technical Regulatory Officer through the Ontek portal of the Ministry of Industry and Technology. The Technical Regulatory Officer logs in to the Ontek portal with his/her TR Identity Number and E-Government password. Ontek selects Module D certification from the New Certification section of the portal, enters the company's information and product information, and sends it to the Technical Expert who makes the evaluation via the portal. The relevant technical expert approves the certification on Ontek by logging in with his/her TR Identity Number and E-Government password. After the approval is ticked; D Module Review and Decision Making Form (ÜFR.010), Module D QMS Review Report if used, test results made in the customer laboratory, Module D Additional Review List, Production Supervision and Control Common Question List and Annex-1 (Annex) are uploaded to the portal and sent back to the Technical Regulation Officer.

The Technical Regulatory Officer re-enters the Ontek portal and assigns a Module D Certificate number with the Certify option, sets the validity date as 1 (One)* year and completes the certification process with the Certify option. The QR code to be added to the certificate is extracted. The QR Code is forwarded to the Product Certification Manager and the Module B certificate of the product is prepared in line with the information in the QR code.

-ÜUB.02 Production Quality Assurance Approval

4.12. If the Module D certification decision is to be made with the External Technical Expert for the product:

4.12.1 The certification process is started by the Technical Regulatory Officer through the Ontek portal of the Ministry of Industry and Technology. The Technical Regulatory Officer logs in to the Ontek portal with TR Identity Number and E-Government password. From the Ontek portal, from the Certification with External Expert section, Module D selects the certification, enters the company's information and product information, and marks the name of the External Technical Expert who made the evaluation. Module D Review and Decision Making Form (ÜFR.010), Module D QMS Review Report if used, test results made in the customer laboratory, Module D Additional Review List, Production Supervision and Control Common Question List and Annex-1 (Annex) are uploaded to the portal. Technical Regulatory Officer assigns Module D Certificate number, sets the validity date as 1 (one)* year and completes the certification process with the Certify option.

The QR code to be added to the certificate is extracted. The QR Code is forwarded to the Product Certification Manager and the Module B certificate of the product is prepared in line with the information in the QR code.

-ÜUB.02 Production Quality Assurance Approval

**NOT: ***The Module D certificate is valid for 3 (three) years from the date of issue and the Module D certificate must be renewed every year by conducting a surveillance audit. Therefore, 1 year validity date is given from the date of publication.

c- F MODULE REVIEW / AUDIT:

F MODULE REQUIREMENTS :

1. The manufacturer must take all measures to ensure that the manufactured measuring instrument conforms to the approved type defined in the EU Type examination certificate (Module B) and to the requirements of the Measuring Instruments Regulation.

2. For Module F product verification, inspections and tests appropriate to the type of product defined in Module B are applied.

2.1. Tests and inspection to verify that the Measuring Instrument conforms to the relevant requirements, at the request of the manufacturer;

Inspection and testing of each measuring instrument or

In accordance with the sampling system according to the lot number of the Measuring Instrument, F Module Sampling Instruction ÜTL.09 is made according to the lot number as specified.

a. Verification of conformity by inspection and testing of each measuring instrument:

At the request of the manufacturer, each measuring instrument is tested and examined separately. In order to verify that this measuring instrument complies with the approved type defined in the Module B certificate and the requirements of the Measuring Instruments Regulation, it is subjected to appropriate tests specified in harmonized European Standards and/or norm documents and/or equivalent tests specified in other technical specifications.

2.3. Statistical Verification of Conformity :

The manufacturer must present the measuring instruments in each batch produced in homogeneous batches. In accordance with the sampling system (F Module Sampling Instruction ÜTL.09), random samples are taken from each batch in the amount specified. All samples taken are individually examined and subjected to the appropriate tests specified in the relevant harmonized European Standards and/or norm documents and/or equivalent tests specified in other technical specifications in order to verify that these instruments comply with the approved type defined in the Module B document and the requirements specified in the Measuring Instruments Regulation and to determine whether these batches are accepted. F Module is verified and approved according to the acceptability number of lots specified in the Module Sampling Instruction (ÜTL.09).

3. The manufacturer is obliged to make the measuring instruments available for inspection by the Ministry of Industry for ten (10) years after placing the measuring instruments on the market for each model of the product receiving the B Module and F Module certificate.

*** If F Module Review will be done at Company Address :**

1. The application is received, reviewed, checked and, if appropriate, the offer is submitted, and the offer replaces the contract when signed. After the contract is signed, the Customer Privacy Statement and Commitment is signed.

- Measuring Instruments Regulation F Module Application Form (ÜFR.003)
- F Module Application Control Form (ÜFR.006)
- Product Certification Offer-Contract (ÜDD.11)
- Customer Privacy Statement and Commitment (ÜDD.17)

3. From the Technical Expert Competency Table (ÜDD.27), the Technical Expert with the competence appropriate to the product to be certified is assigned. (ÜFR.040)

- Since the quality system of the production is not considered in Module F, no Lead Auditor or auditor is assigned.

The product certification manager prepares the audit plan in coordination with the Technical Expert or External Technical Expert..(ÜFR.009) .

- Technical Expert or 1 External Technical Expert is sufficient as technical issues will be covered.

3. Product Certification Manager receives customer confirmation for the date and duration of the audit by phone or e-portal. The assigned Technical Expert goes to the company address on the planned day and time.

3.1. Opening Meeting is held. (ÜFR.041) After the opening meeting, the technical expert checks the laboratory for the tests to be performed.

3.2. Sample or samples are taken according to F Module Sampling Instruction (ÜTL.09). Accuracy tests are performed according to the relevant standard(s) of the product. If the standard of the product is not available, the accuracy tests determined by the notified body are performed. The tests to be performed for the products in our scope are specified in ÜDD.38 F Module Scope Product Based Test Table.

3.3. Module F review questionnaire is completed. (ÜFR.043)

3.4. In case of non-conformity, UFR.063 is used. The company is given time to eliminate nonconformities. (Maximum 90 days)

3.5. After all reports are filled in properly, a Closing meeting is held with the company officials. (ÜFR.041)

3.6. If there is a nonconformity in the inspection and test laboratory evaluation or test results, the audit is stopped and a closing meeting is organized. (ÜFR.041)

3.7. The customer is asked to fill in the Customer Satisfaction Survey Form at the end of the closing meeting. (ÜFR.054)

3.8. After the non-conformity or non-conformities are closed, the Technical Expert issues the F Module Review Result Notification Report (ÜFR.020) and Final Protocol is prepared. Together with the reports, the prepared and signed Final Protocol, the test results are delivered to the Technical Regulatory Officer.

3.9. As a result of the audit, the Technical files and reports and the company's file are reviewed by the Technical Regulatory Officer (ÜFR.012) In case of deficiencies in the reviewed files and reports, the Technical Regulatory Officer informs the relevant person and the deficiencies are eliminated within a maximum of 1 week.

3.10. The Technical Organizing Officer decides to issue or not issue a certificate after review. (ÜFR.012)

*** If F Module Review will be conducted at Sastek A.Ş. :**

1. The application is received, reviewed, checked and, if appropriate, the offer is submitted, and the offer replaces the contract when signed. After the contract is signed, the Customer Privacy Statement and Commitment is signed.

- Measuring Instruments Regulation F Module Application Form (ÜFR.003)
- F Module Application Control Form (ÜFR.006)
- Product Certification Offer-Contract (ÜDD.11)
- Customer Privacy Statement and Commitment (ÜDD.17)

2. The customer company sends the sample of the product to Sastek A.Ş. address. The sample is accepted with ÜFR.033 Sampling Form. The sample is kept until the examination of the Technical Expert.

4. From the Technical Expert Competency Table (ÜDD.27), the Technical Expert with the competence appropriate to the product to be certified is assigned. (ÜFR.040)

- 1 Technical Expert or 1 External Technical Expert is sufficient as technical issues will be covered.

4. When the F Module review will be performed in Sastek, there is no need to plan the review/audit.

4.1. Registration is made in the inspection question list for module F for the conformity of the product to the requirements. (ÜFR.043) .

4.2. The tests to be performed for the products in our scope are specified in the Table of Product Based Tests to be Performed within the scope of ÜDD.38 F Module.

4.3. In case of non-conformity, UFR.063 is used. The company is given time to eliminate nonconformities. (Maximum 90 days)

4.4. If a nonconformity is found in the evaluation of the inspections and tests or in the test results, the inspection is stopped and the client company is informed.

4.5. After the nonconformity or nonconformities are closed, the F Module Inspection Result Notification Report is issued by the Technical Expert (ÜFR.020) and the Final Protocol is prepared. Together with the reports, the prepared and signed Final Protocol, the test results are delivered to the Technical Regulatory Officer.

4.6. As a result of the inspection, the Technical files and reports and the company's file are reviewed by the Technical Regulatory Officer (ÜFR.012) In case of deficiencies in the reviewed files and reports, the Technical Regulatory Officer informs the relevant person and the deficiencies are eliminated within a maximum of 1 week.

After review, the Technical Regulatory Officer decides whether or not to issue a certificate. (ÜFR.012)

4.7. If the F Module certification decision will be made with a Technical Expert working full time within Sastek A.Ş. for the product :

4.8. The certification process is initiated by the Technical Regulation Officer through the Ontek portal of the Ministry of Industry and Technology. The Technical Regulatory Officer logs in to the Ontek portal with his/her TR Identity Number and E-Government password. Ontek selects F Module certification from the New Certification section of the portal, enters the company's information and product information and transmits it to the Technical Expert who makes the evaluation through the portal. The relevant technical expert logs in with his/her TR Identity Number and E-Government password and approves the certification via Ontek. After the approval is ticked; F uploads the Module Review and Decision Making Form (ÜFR.012), the test results and the Final protocol made in Sastek to the portal and sends it back to the Technical Regulation Officer.

Note: No format is needed for the test results. The results can also be issued with a report.

The Technical Regulatory Officer re-enters the Ontek portal and gives the F Module Certificate number with the Certify option, sets the validity date as 5 (five) years and completes the certification process with the Certify option. The QR code to be added to the certificate is extracted. The QR Code is forwarded to the Product Certification Manager and the F Module certificate of the product is prepared in accordance with the information in the QR code.

-ÜUB.03 Declaration of Conformity to the Type Based on Product Verification

4.9. If the F Module certification decision is to be made with the External Technical Expert for the product :

The certification process is started by the Technical Regulation Officer through the Ontek portal of the Ministry of Industry and Technology. The Technical Regulatory Officer logs in to the Ontek portal with his/her TR Identity Number and E-Government password. From the Ontek portal, from the Certification with External Expert section, it selects F Module certification, enters the company's information and product information and marks the Technical Expert who makes the evaluation. It uploads the F Module Review and Decision Making Form (ÜFR.012), the test results made in Sastek, the Final protocol to the portal. Technical Regulatory Officer gives F Module Certificate number, determines the validity date as 5 (five) years and completes the certification process with the Certify option. The QR code to be added to the certificate is extracted. The QR Code is forwarded to the Product Certification Manager and the F Module certificate of the product is prepared in accordance with the information in the QR code.

-ÜUB.03 Declaration of Conformity to the Type Based on Product Verification

5. For Module D, all nonconformities and general opinions arising during the audit are discussed and evaluated. In case of minor nonconformities or major nonconformities that do not affect product conformity, the findings and evidence are reported, signed and signed in the realization period, and inspection and tests are requested. In case of major nonconformity of critical importance affecting product conformity, no inspection and test request is made, Stage 2 audit is not started and a closing meeting is organized. The nonconformity report shall be signed by the authorized person, and if he/she refrains from signing,

this situation shall be indicated and signed by the lead auditor. The audit is repeated after notification that corrective and preventive actions have been taken.

6. For Module D; the lead auditor or auditor follows up whether the nonconformities identified in the stage 2 audit have been eliminated. In this context, the closure information and applications reported by the company are evaluated and returned to the company if not deemed appropriate. The company must close the nonconformities within 90 days at the latest from the date of identification.

7. The tests of the product are carried out in Sastek laboratory / subcontractor laboratory. If needed, Sastek may cooperate with laboratories accredited by TS EN ISO/IEC 17025 or laboratories audited and traceable by Sastek, or the tests may be performed in the customer's laboratory, provided that their suitability is approved.

If Module D requires inspection and testing in the laboratory of the manufacturer or notified or public institution under the supervision of auditors, the inspection and tests stipulated in the relevant standard are carried out; the audit team evaluates the test results and makes this evaluation;.

- Examination of the test results report,
- Compliance with process control outputs,
- The appropriateness of the calibrations of the measurement devices and equipment used in the experiments
- Accuracy of the test method and
- It does the test in the context of the competence of the personnel performing the test to perform the tests.
- Examination and testing is carried out by personnel with the necessary qualifications and a report is issued

8.. The audit team conducts production control and surveillance assessment. In this context, it observes, monitors and evaluates whether all production and control activities in the process from input to product delivery are carried out without interruption and in accordance with the documents.

9. Nonconformities and Corrective actions (For Module B, D and F)

- In order for the customer to receive document approval, corrective actions related to all nonconformities identified during the certification audit or review must be completed and accepted by Sastek.

- Regarding the nonconformities identified in the Inspection/Audit, it is the authority and responsibility of the lead auditor or Technical Experts to follow up whether the nonconformities have been eliminated or not. In this context;
  - The company plans the corrective actions to be implemented and notifies Sastek with a nonconformity report within 30 days.
  - The lead auditor, auditor or Technical Experts verify and confirm that the root cause of the nonconformity has been correctly identified, that the actions to be taken will be sufficient to eliminate and prevent recurrence of the nonconformity, and that the deadlines have been complied with.
  - If the lead auditor, auditor or Technical Experts consider the activities proposed to prevent the recurrence of nonconformity as insufficient, they send the nonconformity report back to the company without approving it, stating the reasons.
  - Regardless of the size, the company must close the nonconformities within 90 (ninety) days at the latest from the date of writing. If the nonconformities cannot be eliminated within this period, the application is deemed invalid and this situation is notified to the customer in writing. The audit team prepares a nonconformity form and an inspection result notification report and forwards the audit documents to the product certification directorate for the purpose of reviewing the certification.

- **If it is understood that the nonconformities have been corrected, an additional assessment activity is required, the customer wants this additional activity to be performed and Sastek agrees; the assessment process is repeated.**

- Follow-up audit is performed for major nonconformities. However, for nonconformities that can be corrected with a document, the requirement for follow-up audit can be removed by the decision of the audit team. Evidence of corrective actions taken for minor/major nonconformities are sent to the lead auditor, auditor or Technical Expert within the period specified by the company.
  - All records submitted by the Customer must be certified by electronic signature or similar,
  - There must be a signature/stamp of the authorized person or company. Registrations that do not bear this marked information are not accepted.
- The customer is obliged to keep records of complaints about the products subject to certification; to take appropriate measures (if any) regarding the defects identified and to keep records of the measures implemented. The lead auditor auditor or Technical Expert shall indicate the findings of this situation in his/her report.
- After the completion of the audit, an audit report is prepared by the lead auditor, auditor or technical expert within 10 (ten) days at the latest and a copy is sent to the client upon request.

10. Follow-up audit

- Sastek;
  - that the customer has removed the reasons for the suspension of its certificate,
  - Major nonconformities detected during the audits and minor nonconformities decided on the spot have been eliminated and
  - For the purpose of determining that corrective actions for non-conformities are effectively implemented,

  can conduct follow-up audits.
- In the absence of a justified and valid reason, the follow-up audit shall be conducted by the audit team that conducted the original audit.
- After Sastek is notified in writing of the elimination of the reasons requiring follow-up audit; the audit is carried out on the date determined by the Product certification manager together with the customer.
- After the production site inspection, if the customer cannot prove that the nonconformities have been eliminated within the period given for the follow-up audit, the application is canceled. In audits carried out less than 30 days before the expiry of the validity period of the certificate, a period of at least 7 days before the validity period of the certificate is given to close the nonconformities. If there is a nonconformity that is not closed at the end of this period, the validity of the document is terminated.
- Nonconformities are verified by the lead auditor and a follow-up audit file is created.

- **Corrective action assessment and follow-up report (ÜFR.047)**

11. Review of the audit

The audit file is examined, evaluated and reviewed by the Technical Regulation Officer under the supervision of the product certification manager in terms of the compliance of all works and transactions in the process from the application to the approval of the product certification manager with the relevant regulation, standards and Sastek's conformity assessment documents. (B, D and F Module)

12. Certification decision

- For D Module Certification, the Certification committee reviews the compliance of the product with the 2014/32/EU Measuring Instruments Regulation and the reference standard requirements of the certification activities; reviews and approves the review and approvals of the product certification manager regarding the completeness of the file and the

Technical Regulatory Officer regarding its compliance; evaluates the issues of impartiality and confidentiality during the audit, whether the customer has complaints and objections and customer satisfaction survey results; verifies the scope, module/system, etc. information regarding the certification and makes the certification decision. **If the decision is negative, the customer is notified with the reasons.**

- For B and F Module certification, the Technical Regulatory Officer evaluates the compliance of the certification activities with the 2014/32/EU Measuring Instruments Regulation and the reference standard requirements; the completeness of the file, reviews, examines, evaluates the issues of impartiality and confidentiality during the audit, whether the customer has complaints and objections and customer satisfaction survey results; verifies the scope, module/system, etc. information about the certification and makes the certification decision. **If the decision is negative, the client is notified with the reasons.**

- **B Module Review and Decision Making Form (ÜFR.011)**
- **D Module Review and Decision Making Form (ÜFR.010)**
- **F Module Review and Decision Making Form (ÜFR.012)**

13. Certification documentation

- In accordance with the decision of the Certification Committee in D Module certifications and of the Technical Regulation Officer in B and F module certifications, the certificate of conformity and its annexes bearing the signature of the general manager are given to the customer by the product certification manager in return for signature.
- Within the scope of Sastek 2014/32/EU Measuring instruments regulation and in accordance with the requirements of the reference standard; on the document and / or in the annex to include the information / documents that are the requirements of the relevant regulation and module;
  - EU Type examination certificate (Module B)
  - Declaration of conformity to the type of quality assurance regarding the manufacturing process (Module D)
  - Declaration of conformity to type based on product verification (Module F; Documents)
- **Mode B, Information to be included in the EU Type examination certificate additional final protocol; instruction on the content of the protocol ÜTL.04 and**

- **The information to be included in the additional final program of the declaration of conformity to type based on Module F product verification is issued in accordance with the instruction ÜTL.05 on the content of the protocol.**

14. Database of certified products

- Regarding the products certified by Sastek; the definition of the product, the standard and other normative documents on which the conformity is based, the definition of the customer, the regulation, the module / system, etc. information; Information required to be included in the approval certificate and / or annex within the scope of the relevant module of the 2014 / 32 / EU Measuring Instruments Regulation is given or added. In this case, it is stated that the documents are valid with their annexes and the document and annex information on the certified products and the revision information resulting from the changes, taking into account the restrictions, if any, in the relevant regulation, are kept open to access on the www.sastek.com.tr web address.
- The information of the certificates of the certified companies is registered and published on the Sastek web page by the Deputy General Manager.
- Within the scope of public information, an inquiry can be made by selecting MID Certification from the “Certificate Inquiry” link from www.sastek.com.tr web address and entering the certificate (Establishment Document No.)

number of the certificate issued. The scope of the certificate, its validity date and the company to which it was issued can be seen.

15. Surveillance and other audits

15.1. .Surveillance audit (in D Module Certifications)

- Surveillance audit; In D Module certifications, it is carried out at least 1 (one) time in 12 (twelve) months during the validity period of the document in order to check whether the customer maintains the conditions and conformity of the certification. Surveillance audits are not postponed for any reason. At the request of the customer, the surveillance audit can be carried out before 12 months.
- Based on the period specified in the contract, the Product Certification manager contacts the customer 3 months prior to the expiry date of the document validity period and agrees on the audit date.
- Planning of the audit, assignment of auditors, conducting the audit and actions to be taken regarding nonconformities detected in the audit are carried out as in the certification audit.
- The following issues are examined in the surveillance audit:
  - Verification of actions taken in relation to nonconformities identified in the previous audit,
  - Complaints
  - Changes in planned activities aimed at continuous improvement,
  - Review of changes,
  - Changes to technical documentation (if any),
  - Whether the continuity of process conditions is ensured,
  - Special conditions in the module;
    - Type of measuring instrument,
    - Technical file,
    - Inspection and test data,
    - Calibration data,
    - Qualifications and approval of personnel performing final inspection and sealing,
- **D Module Surveillance audit report (ÜFR.048)**

16. Change audits (D, B and F modules)

- Customer can request changes in scope, company title, address, branch address (if any). For this, Sastek applies to the product certification directorate with the relevant form. The product certification manager evaluates the change request. If it is not deemed appropriate, the situation is notified to the customer with the reasons. If the customer objects, necessary measures are taken in accordance with the relevant procedure.
  - If the customer change request is a change of address, a re-audit is carried out at the customer's workplace and an audit/inspection is carried out.
  - When there is a request for D Module scope expansion (if the product to be added to the D module is in the same product group as the product / products in the existing D Module), the existing certification documents are reviewed, a new decision can be made and an addition can be made to the existing certificate. After the certification process, the revision number is given to the previous D Module certificate. D Module annex (ÜUB.02- EK1 Annex) is prepared to cover all products. Updates are made by the Technical Regulatory Officer and the relevant technical expert through the existing D Module through the Ministry of Industry and Technology. While updating, D Module Annex, Review and Decision Making records and existing D Module certification reports are uploaded to the Ministry of Industry and Technology portal.
  - B module scope expansion can be made for products that are identical in terms of the same product group and technical specifications (Model addition, etc.), after the necessary tests are performed. The test results and the Final

protocol of the existing B Module certificate are updated to cover all models. Updates are also made through the Ministry of Industry and Technology. With the Technical Regulatory Officer and the relevant technical expert, the test reports, review and decision-making records of all products and the Final protocol (ÜUB.01-Ek1 Final Protocol) are uploaded to the ministry portal. Revision is also made on the existing certificate by giving a revision number.

- If requested in the F Module, the change of address title can be made by submitting official documents and requesting it, since there is no change in the product. Updates are made through the Ministry of Industry and Technology. With the Technical Regulatory Officer and the relevant technical expert, test reports, review and decision-making records of all products and the Final Protocol (ÜUB.03-Ek1 Final Protocol) are uploaded to the ministry portal. Revision is also made on the existing certificate by giving a revision number.
- The transition period for amendments is the period determined by the institution publishing the amendment. In cases where there is no such period, this period is 1 year.
- The customer retains copies of the technical documents, as well as copies of the certificates of conformity and annexes, for 10 (ten) years from the latest date of manufacture of the products. In cases where the manufacturer is not located in Turkey, these documents are kept for the same period of time by offering the product to the market.

17. Whistleblower audits

- In case of nonconformity detected in market surveillance and inspections carried out by the relevant institutions and / or other complaints based on objective evidence; With the approval of the General Manager, an out-of-program audit can be carried out by informing the customer. These audits are notified to the company before a period of time in which it will not change the conditions that cause the audit. In audits;
  - Complaint subject,
  - The need to follow up on previous surveillance audits,
  - Special conditions for the approval of the system and
  - The manufacturing process, criteria and techniques and significant changes in its organization are examined.

- If the client does not accept the audit, it is suspended with the recommendation of the General Manager and the decision of the certification committee and the company is notified in writing. This situation is included in the contract.
- In cases where the certificate is suspended, the relevant ministry and the authorized body carrying out market inspection and surveillance shall be informed.

18. Changes affecting certification (B, D and F modules)

- Sastek evaluates every change in the relevant regulations, certification program, reference standard, product standard and other legal and regulatory requirements. If deemed necessary by Sastek, these changes are notified to the customer and additional evaluations can be made..
- The customer shall immediately notify Sastek of any changes (legal status, business area, organizational structure, processes, quality system, documentation, technical specifications of the product, etc.) that affect its ability to fulfill the requirements for conformity verification.
- It is verified that the changes notified by Sastek and the changes contemplated by the customer have been implemented. The verification activity depends on the content of the change and is communicated to the customer. This verification activity consists of evaluation, review and decision stages. The decision may be in the form of extension/reduction of the scope of certification, surveillance audit and revised documents are published.

- Form for monitoring changes affecting certification (ÜFR.049)

19. Maintaining document approval (Module B, D and F)

- The validity of the certificate of conformity is maintained in accordance with the terms of the contract. This is accomplished through an audit or inspection of the customer's workplace, within the scope of the legislation of the relevant product. If, in any way, a non-compliance with the terms of certification is detected, Sastek will take appropriate action (additional follow-up audit, reduction of the scope of certification, suspension of certification or withdrawal of certification).
- Sastek notifies the relevant ministry of the denial, reduction, suspension or withdrawal of the certificate; situations affecting the scope and conditions; information requested by the market surveillance authority; and services provided abroad, if any.

20. Suspension of the certificate

- In the event that the production of the product is interrupted or cannot be produced, the suspension or revocation of the relevant certificate may be requested by the customer.
- The decision to suspend the certificate is made by the certification committee in Module D and by the Technical Regulatory Officer in Module B and F. The suspension is notified to the client in writing. The customer may use legal remedies regarding the suspension or revocation of the certificate. The suspension period is maximum 6 (six) months.
- At the end of this period, if the reason for the suspension of the certificate has not been removed, the certificate will be automatically canceled.

In case of a decision to cancel the certificate due to non-conformity, the contract between Sastek and the customer is terminated and the certificate of conformity for the product is returned to Sastek by the customer.

- In the event of suspension or revocation of the certificate, the Client shall cease the use of all advertising materials, logos, conformity assessment identification numbers referring to the certification.
- Sastek suspends the customer's certificates if the following conditions are met.
  - Continuous or serious inability of the customer to meet the requirements of the certified management system and the certification requirements,
  - The customer does not allow the scheduling of surveillance audits, recertification audits and whistleblowing audits,
  - The customer requests suspension of the certificate,
  - Major nonconformities are found during inspections or minor nonconformities are not corrected within the given time,
  - Failure to comply with certification rules and certification requirements,
  - Causing misperception of certification; misuse or misappropriation of logos, documents and related documentation; and
  - Failure of the customer to fulfill its financial obligations to Sastek
- If the customer notifies Sastek in writing that the reason for suspension has been removed, an audit may be carried out at the company address to confirm the situation. If it is understood that the reason for suspension is eliminated as a result of the audit, the suspension is lifted by the decision of the Certification committee in the relevant D Module or by the decision of the Technical Regulatory Officer in B and F Modules. This decision is notified to the customer in writing and the suspension is made from the Ontek portal of the Ministry of Industry and Technology. In cases where the reason for suspension is not eliminated, the document is canceled.
- The scope and duration of the audit for lifting the suspension is determined by the Product Certification Manager according to the reason for the suspension.

21. Cancellation of the certificate (B, D and F Module)

A. Cancellation of the certificate after suspension of the certificate

- If the customer does not apply to Sastek in writing for a follow-up audit within 6 (Six) months after the decision to suspend the certificate, the certificate will be canceled.

- The Customer may request Sastek to cancel the certification in writing. There is no time limit for this. The request is reviewed and approved by the product certification manager and the customer is informed in writing.
- In case of revocation of the certificate, the customer ceases to use the certificate, logo, notified body number, etc. It relinquishes its rights within the scope of the canceled document and pays the unpaid fees.
- After the cancellation of the certificate, the customer removes the document, logo, notified body no etc. and all kinds of correspondence, promotion, advertising material from the product label. In case the customer fails to fulfill these, Sastek shall take legal remedies for the compensation of material and moral damages arising from this reason.
- In cases where the customer does not request document renewal, the production of the product covered by the document stops or the workplace is closed, the document is canceled by Sastek and the situation is made through the Ontek portal of the Ministry of Industry and Technology.

- **The certificate is canceled in the following cases:**

  - The customer requests or ceases its activity within the scope of the document or becomes bankrupt or its legal entity changes,
  - Failure to accept the terms of suspension or to remove the grounds for suspension,
  - Failure to provide confirmation for follow-up audit at the end of the suspension period,
  - Failure to close the nonconformities identified in the follow-up audits carried out to lift the suspension within the stipulated period,

B. Cancellation of the certificate directly (without suspension)

- The customer's misleading and unfair use of the document, logo, notified body number, etc. in areas other than the product specified in the document,
- The customer cannot be found at the specified workplace address,
- Falsification of documents and annexes and
- Not accepting the surveillance audit.

22. Witness Inspection

Witness Audit can be performed by the Turkish Accreditation Agency to any company certified by Sastek A.Ş. within the scope of TS EN ISO 17065 Standard. In the contracts made with customer companies, confirmation of this issue is received from the customer. In a subject determined by Türkak within the scope of Sastek, an audit of a company certified or to be certified with D Module, if it is B Module, at Sastek office or company address, if it is F Module, it is done together with Türkak auditors and Sastek audit team at the company address. Türkak auditor observes how the Sastek audit team or Technical Expert performs the audit or inspection.

23. Reducing and expanding the scope of the document

a) Reducing the Scope of the Document

B MODULE: The scope of the B Module certificate can be reduced upon customer request or for a justified reason (when the manufacturer company gives up the production of some of the products covered by the certificate, when there are changes in the production of the products that do not meet the basic requirements of the models in the production of the products, etc.). The Final Protocol is revised by a technical expert who has been appointed and has competence related to the product. Revision is also made through the Ontek system of the Ministry of Industry and Technology and the scope reduction is completed. A new certificate is issued and sent to the customer. The revision made to the customer is notified in writing, the old certificate is withdrawn and the new document is delivered after the old document is returned from the customer.

D MODULE : When the validity date of the B Module certificate of the products attached to the existing D Module of the customer company expires, the scope is reduced in the D Module certificate. D Module scope and company file are checked and reviewed by the technical regulation officer. Afterwards, the scope of the D Module certificate is reduced by the

Certification Committee by making a scope reduction decision. The necessary documents are revised from the Ontek system of the Ministry of Industry and Technology and the document is re-issued.

b) Expansion of Document Scope

B MODULE : For new products or products in the same scope as the certified product, the scope of the document can be expanded after the report and technical file check. For this, the products to be included in the scope of the certificate must be in the same Measuring Instruments group. The evaluation process is repeated taking into account the differences as in the first certification. The Final Protocol is revised by a technical expert who has been appointed and has competence related to the product. Revision is also made through the Ontek system of the Ministry of Industry and Technology and the scope expansion is completed. A new certificate is issued and sent to the customer. The revision made to the customer is notified in writing, the old certificate is withdrawn and the new document is delivered after the old document is returned from the customer.

D MODULE : New products can be added to the products covered by the D Module of the customer company. For this, the products to be included in the scope of the document must be in the same Measuring Instruments group. In addition, a new product is added to the Annex (Annex.1) document and the D Module scope and company file are checked and reviewed by the Technical Regulation Officer. Afterwards, the scope of the D Module certificate is expanded by the Certification Committee by making a scope expansion decision. The necessary documents are revised from the Ontek system of the Ministry of Industry and Technology and the document is re-issued.

24. Registries

- Sastek does not share customer information obtained or created during the certification activities and audit process with third parties without the written consent of the customer. The management system and technical records created in this process are kept in complete confidentiality. Necessary security measures are taken in transportation, transmission and transfer. Sastek prepares an impartiality procedure and a confidentiality instruction for the protection of the information it obtains; a confidentiality-neutrality agreement has been signed with all employees and commitments have been received; it receives commitments from the audit team in the same scope before each audit and has established and implemented a records control procedure for the safe protection of the records created.

  - **Procedure for managing impartiality (ÜPR.01)**
  - **Procedure for control of records (ÜPR.08)**
  - **Confidentiality-impartiality commitment (ÜDD.09)**

25. Complaints and appeals

- **Sastek** takes into account the complaints, objections and disputes made by any person or institution/organization regarding certification and audit activities, personnel, procedures, activities of its customer within the scope of certification, etc. and evaluates them in accordance with the relevant procedure and in confidentiality. Customer complaints regarding service quality are provided in writing or verbally as a result of surveys and customer satisfaction is also evaluated within this scope. The said procedure is available for public access on the website www.sastek.com.tr .

  - **Procedure for evaluating complaints and appeals (ÜPR.06)**

26. RELATED DOCUMENTS

Related documents are indicated under each heading.

27. RECORDS

Records resulting from the implementation of this procedure shall be kept for 10 (ten) years.

28. RECORD OF CHANGE

Revision No	Date	Description
00	10.05.2018	First Publication
01	30.10.2018	What to do if the assessment of correction activities requires additional activities has been added.
02	29.11.2018	The audit scope of the systems is explained to be clear and understandable.
03	24.10.2019	Audit definition has been made on module basis. 4.5.5 Audit has been corrected to activities by Module. 4.11 Reference to the instructions prepared on the information to be included in the additional final protocol • -Water and Electricity meter inspection and test plans have been added to RP:10 for MID Module F. Resources utilized were added (Art:2)
04	27.02.2023	Procedure has been reviewed and updated, B, D and F Module audits have been made more efficient. The certification process from the Ministry of Industry and Technology has been explained. Document Number has changed.
05	23.03.2023	Conducting the General Review and Module F in Sastek is explained.
06	18.04.2023	Scope expansion topic added.
07	19.01.2024	Article 4.20 has been added.
08	22.03.2024	Module Requirements B, D and F have been added.