

#### 1. Introduction:

- This program is the certification program for measuring instruments given in the annex to the Sastek conformity assessment Handbook.
- This program regulates the principles regarding the form and conditions of applying to Sastek for product certification, certification needs and objectives, issuance and execution of the certificate.
- Sastek carries out product evaluation and certification procedures in accordance with the relevant product certification procedure in accordance with the relevant product standards, within the plan prepared by experts. The prepared plan is generally as follows.

# For measuring instruments; 2014/32/EU Regulation on measuring instruments

Module	Description
Module B	EU Type review
Module D	Declaration of conformity to type based on quality assurance of the manufacturing process
Module F	Declaration of conformity to type based on product verification

#### Quality module references for measuring instruments

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

- This program and its amendments are published on Sastek's website (www.sastek.com.tr), sent to the eligible customer within the scope of the offer/contract and signed.
- According to Sastek's current procedures, companies that prove full compliance with the requirements
  of the relevant product standards are certified.

# 2. Validity:

The duration of Module B certifications is 10 (ten) years, the duration of Module D certifications is 3 (three) years (but if the surveillance audit is carried out every year and continuity is ensured, it is extended for one year, the date is given as 1 (one) year in the certificate), the duration of Module F certification is 5 (five) years, it is renewed upon request at the end of 5 years.

#### 3. Certification Committee

The program committee is made up of those who are capable of representing the following parties and who are shown in the organization chart, staff list. It is the committee that makes the Decisions for Module D Certifications.

Academics



- Public employees
- Private sector employees
- Elected from STK (civil society organization) members.

# 4. Qualifications of the Personnel to Take Part in the Review/Audit

The competency of the personnel who will take part in the Review or Audit is defined below as specified in EA-2/17 and TURKAK R.10-13 Guidelines.

**Lead auditor:** It is the personnel leading the auditors and / or Technical Experts who take part in the Module D conformity assessment activities to be carried out by the notified body in accordance with the Measuring Instruments Regulation.

**Auditor:** It is the personnel who are involved in the planning of Module D audits within the scope of Module D conformity assessment activities to be carried out by the notified body in accordance with the Measuring Instruments Regulation, and who present and report to the technical regulation officer who conducts and evaluates the QMS audit.

**Technical Specialist (including External Technical Specialist):** Within the scope of conformity assessment activities to be carried out by the notified body in accordance with the Measuring Instruments Regulation, the personnel who can take part in matters related to competence, perform planned examinations and/or audits and report the results of examinations and/or audits.

#### 5. Measuring Instruments Regulation Certification Procedure

# 5.1 Certification preparation

#### 5.1.1 Application

For application, please visit www.sastek.com.tr and call 0312 385 35 34. The application can be made directly or electronically to Sastek with the relevant application form and annex documents available on the website.

The application is checked, if there are any deficiencies, it is completed and reviewed to ensure that the request can be fulfilled.

Sastek has the resources and technical capacity to certify the products specified in its scope. It does not accept applications for products that are outside its scope, for which product type, normative document or certification program has not been determined, and applications within the scope of equivalence.

# 5.1.2 Making a contract

Following the approval of the application; a proposal which clearly states the content of the service to be provided, including information on the certification program, document, logo, use of the notified body number, audit period, fee and payment, is prepared and sent to the customer. At this stage, the client may request that certain issues be evaluated. If the offer is deemed appropriate by the parties, it is signed and takes the status of a contract.

### **5.2 Certification stages**

#### 5.2.1 Planning of the certification

What will be done in the certification process is planned in this context. Certification plan with;

- Product name, model, class, type, etc.
- Product-related standards/criteria, system and scope



- Which examinations and tests will be made for the certification and in which laboratory they will be executed
- The number, packaging, storage and delivery of samples to be taken for inspection, test and witness samples
- Who will be the observer when inspections and tests are carried out in the cooperation or customer laboratory
- (If any) Special explanations related to inspection and test
- 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
- Quality management system requirements
- Adequacy of quality control facilities
  - Conditions to be required in the personnel responsible for the laboratory
  - What are the equipment for inspection and testing
  - Routine inspections and tests; how input control is performed
- The conditions of mid-control, the amount of samples to be taken and special conditions, if any
- Information on the certification method
- Devices that require calibration; is prepared

# 5.2.2 Planning and performing the audit

The audit plan includes the appropriate team of auditors, the date and duration of the audit and, if the **module** requires, the laboratory where the inspection and tests will be performed. Client approval is obtained for both these information and the resumes of the auditors and customer requests are evaluated, if any.

# 5.2.3 Performing the audit

- B Module certification can be done at the customer company or it can be examined at the desk in Sastek
  office. D Module Certification is carried out at the production site of the customer company. F Module
  certification is examined for product verification at the customer company.
- In D Module certifications, a pre-audit is performed with 1 lead auditor or 1 auditor. In this context, the quality management system is reviewed and examined (Stage 1 Audit).
- The D Module Audit (including the F Module review if the B Module review will be conducted at the client company) starts with an opening meeting with the participation of the audit team and company officials.
- The audit is carried out on a module basis in accordance with the Measuring Instruments Regulation Certification Procedure (ÜPR.05).
- All nonconformities and general comments arising during the audit are discussed and evaluated. Minor
  nonconformities that do not affect product conformity and major nonconformities that affect critical product
  conformity are identified; The duration of implementation of corrective actions is decided, reported together
  with findings and records; A follow-up audit is opened for major nonconformities affecting product
  conformity; The nonconformity report is signed by the authorized person, if he/she refrains, the situation is
  stated and signed by the lead auditor and a closing meeting is organized.



• The follow-up of whether the identified nonconformities have been eliminated is carried out by the lead auditor or auditor in D Module Audit, and by the Technical Expert in B Module and F Module. In this scope, the closure information and applications reported by the company are evaluated and returned to the company if deemed inappropriate. The company must close the non-conformities within 90 days from the date of identification. An additional assessment activity is required to verify that the nonconformities have been corrected, if the customer wants this additional activity to be performed and Sastek agrees; the assessment process is repeated.

If the module requires inspection and testing in the manufacturer or notified / public institution laboratory under the supervision of auditors, the inspections and tests in the relevant standard are carried out; the audit team evaluates the test results and considers;

- Examination of the test results report,
- Compliance with process control outputs,
- The appropriateness of the calibrations of the measuring instruments and equipment used in the
  experiments,
- · Accuracy of the test method and
- The competence of the personnel performing the experiment to perform the experiments, in making this
  evaluation.
- Within the scope of production control and surveillance assessment, the audit team observes, monitors
  and evaluates whether all production and control activities in the process from entry to product delivery
  are carried out without interruption and in accordance with the documents.

#### 6. Nonconformities

- In order to receive certification approval, the client must complete corrective actions for all nonconformities identified during the certification audit and these actions must be accepted by Sastek.
- Regarding the nonconformities identified in the audit, it is the authority and responsibility of the lead
  auditor or, if any, the auditor or Technical Expert to monitor whether the nonconformities have been
  eliminated. 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 verifies and confirms 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 met.
  - If the lead auditor considers the activities proposed to prevent the recurrence of nonconformity as
    insufficient, the lead auditor sends 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 conformity notification report together with the nonconformity form and forwards the audit documents to the certification management in order to review the certification.
- 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 within the period specified by the company.

- All records sent by the customer;
  - It must be approved by electronic signature or in a similar way, and must have the signature/stamp of the authorized person or company. Records that do not bear this marked information are not accepted.
- The customer is obliged to keep records of complaints about the products to be certified; take appropriate precautions regarding the identified defects (if any) and keep records of the precautions implemented.

#### 7. Program Audit Period

Module B Certificate is valid for 10 (ten) years.

Module D Certificate is valid for 3 (three) years. However, the continuity of the system is checked by conducting a surveillance audit every year.

Module F Certificate is valid for 5 (five) years.

## 8. Follow-up Audit

- Sastek can conduct follow-up audits for the purpose of
  - establishing that the reasons for the suspension of the client's certificate have been removed
  - ensuring that major nonconformities detected during the audits and minor nonconformities decided on the spot are eliminated and,
  - determining that corrective actions for non-conformities have been effectively implemented.
- The follow-up audit is carried out by the audit team that conducted the original audit, unless there is a
  justified and valid reason.
- After Sastek has been notified in writing of the elimination of the reasons requiring a follow-up audit,
   the audit will take place on the date determined by the planning officer together with the customer.
- 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 the audits carried out less than 30 days before the expiry of the validity period of the document, at least 7 days before the validity period of the document is given for the elimination of 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.

#### 9. Review

The audit file is examined and evaluated by the Technical Regulatory Officer in terms of compliance with the relevant regulations, standards and Sastek's conformity assessment documents of all works and procedures in the process from the application to the approval of the certification manager.

#### 10. Certification Decision and Issuance of the Certificate

- Module B and F certification decisions are made by the Technical Regulatory Officer.
- For Module D, the certification committee examines the compliance of the product with the relevant regulation and the certification activities with the requirements of the reference standard; examines the approvals of the certification manager on the completeness of the file and the review officer on its conformity; evaluates the issues of impartiality and confidentiality during the audit, the results of the customer satisfaction survey and whether the customer has complaints and objections; verifies the scope, system, etc. information



on certification and makes the certification decision. If the decision is negative, the reasons are notified to the client in writing.

#### 11. Surveillance Audit (For Module D)

- Surveillance audit; It is carried out at least 1 (one) time per year during the validity period of the certificate in order to check whether the customer maintains the conditions and compliance with which the customer is certified. Surveillance audits are not postponed for any reason. At the request of the customer, the surveillance audit can be carried out before one year.
- Based on the period specified in the contract, two months prior to the expiry date of the document validity period, the customer is contacted and the audit date is agreed upon.
- 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 regarding nonconformities identified in the previous audit,
  - Complaints,
  - Changes in planned activities aimed at continuous improvement,
  - Review of changes,
  - Changes in technical documentation (if any),
  - Whether the continuity of process conditions is ensured,
  - Special conditions in the module;
    - Technical file
    - Inspection and test data (if available)
    - Calibration data (if available)

#### 12. Change Audits

The customer may request changes in scope, company title, address, branch address (if any). For this, the customer applies to Sastek A.Ş.. The request for change is evaluated, and if it is deemed inappropriate, the situation is notified to the customer together with its reasons. If the customer objects, necessary precautions are taken in line with the relevant procedure. If the customer's change request is not deemed appropriate, a new audit is conducted. The transition period for changes is the period determined by the institution that published the change. In cases where there is no such period, this period is 1 year.

The Customer shall retain copies of the technical documentation, the certificates of conformity and all attached documents for a period of 10 (ten) years from the latest date of manufacture of the products. In cases where the manufacturer is not located in Turkey, these documents shall be kept for the same period of time by the person offering the product to the market.

#### 13. Whistleblower audit

- In case of nonconformity detected in market surveillance and inspections carried out by the relevant institutions and / or other complaints based on objective evidence; 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. During audits;
  - Subject of the complaint,
  - Need to follow up on previous surveillance audits,
  - Special requirements for the approval of the system and
  - Manufacturing process, criteria, techniques and significant changes in the organization are examined.



- If the customer does not accept the audit, it is suspended upon the recommendation of the General Manager and the decision of the certification committee, and the company is notified in writing.
- In cases where the certificate is suspended, the relevant ministry and the authorized body conducting market surveillance and inspection are informed.

#### 14. Continuation, Suspension and Revocation of the Certificate

• The validity of the certificate of conformity is maintained in accordance with the terms of the contract. This is carried out within the scope of the legislation of the relevant product and according to the relevant system document. 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).

#### A. Suspension of the certificate

- Suspension or revocation of the relevant certificate may be requested by the customer in the event that the production of the product is interrupted or cannot be produced.
- The decision to suspend the Module D Certificate is made by the certification committee and the decision to suspend the Module B and F Certificates is made by the Technical Regulatory Officer. The suspension is notified to the customer in writing and the suspension is made on the Ministry of Industry portal. 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.

- The Customer stops the use of all advertising materials, logos, Notified body number referring to the certification in case of suspension or revocation of the certification.
- Sastek suspends customer documentation if the following conditions are met.
  - Continuous or serious failure of the customer to meet the requirements of the certified management system and certification requirements,
  - The client does not allow the scheduling of mid-term audits, recertification audits and Whistleblower audits,
  - The client 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 incorrect use of documents related to the use of logo, certificate and notified body number and
  - Failure of the customer to fulfill its financial obligations to Sastek.
- If the customer notifies Sastek in writing that the reason for the suspension has been removed, an audit may be carried out at the workplace to confirm the situation. If it is understood that the reason for suspension is eliminated as a result of the audit, the suspension is revoked by the relevant committee decision. This decision is notified in writing to the client and the ministry. In cases where the grounds for suspension are not removed, the certificate will be canceled.
- The scope and duration of the inspection to revoke the suspension will be determined according to the grounds for suspension.

#### B. Revocation of the certificate



# B1. Revocation 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 certification manager and the client is informed
  in writing.
- In case of revocation of the certificate, the customer stops the use of documents, logos, etc. Relinquishes its rights within the scope of the canceled document and pays the unpaid fees.
- After the cancellation of the certificate, the customer removes all kinds of correspondence, promotional materials with documents, logos, etc. from the product label. In the event of nonfulfillment by the Customer, Sastek notifies the ministry of the situation and applies for legal remedies for the compensation of material and moral damages arising from this reason.
- In the event that 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. (Cancellation procedures are also carried out through the Ministry of Industry portal).
- The certificate is canceled in the following cases.
  - The client 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,

## **B2.** Direct revocation of the certificate (without suspension)

- The customer's misleading and wrongful 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 their attachments and
- Failure to accept the surveillance audit; in cases where the document is canceled directly (without suspension)

# 15. Changes Affecting Certification

- 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 assessments may be made.
- The customer notifies Sastek immediately of any changes (legal status, business area, organizational structure, processes, quality system, documentation, product specifications, etc.) that affect its ability to meet 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 assessment, review and decision phases. The decision may take the form of an extension/reduction of the scope of certification, surveillance audit, and revised documents are published.

## 16. Objection to Results and Complaint

Objections and complaints that may be received during the conformity assessment process or during finalization are evaluated and finalized according to the relevant procedure. All complaints about the audit team, Technical Experts or Sastek employees or the service, as well as appeals against certification decisions, are reviewed, ÜDD.24/Rev.03-23.03.2023



evaluated and finalized by the management/relevant committee. If the objection and complaint are of a technical nature, an opinion is obtained from another auditor who has not participated in the audit and has technical competence.

## 17. Confidentiality and Impartiality

Sastek is committed to maintaining its impartiality, independence and confidentiality policy in all of its conformity assessment activities. It takes all necessary measures in line with the relevant procedure for all risks that may damage impartiality through 'risk analyzes' carried out together with the evaluation meetings held with the impartiality committee. All party information obtained through conformity assessment activities is considered confidential.

#### 18. Use of Trademark, Logo and Notified Body Number

Instructions for Use of Document Logo and Notified Body Number are shared with the relevant party and/or access is provided via internet/web address. In addition, the customer company signing the certification contract is deemed to have accepted the terms contained in the instructions for the use of the Certificate-logo and notified body number, and the terms of the Audit periods fee and payment instruction. It is the responsibility of the customer to follow the update of the relevant instruction on Sastek's web page.

#### 19. Mutual Duties and Responsibilities

#### 19.1 Duties and responsibilities of the client

Customer for conformity assessment;

- 1. Complies with all written and verbal information and instructions sent by Sastek.
- 2. Appoints a staff member to ensure continuity in management system and product performance.
- 3. Ensures that the management team can enter all open and closed places of the workplace during working hours and access all records.
- 4. Fulfills the legal requirements and relevant standard requirements for the product.
- After certification, it informs Sastek about possible changes in the product and organizational structure.Cannot put the product on the market before these changes are approved by Sastek.
- 6. Records of the activities within the scope of conformity assessment carried out by Sastek are kept during the validity period of the certificate.
- 7. If changes are made to the documents, the controlled copy is forwarded to Sastek. In order to evaluate the effect of the changes made on the product, additional audits are carried out for a fee if necessary.
- 8. Fulfills the requirements of the changes in the conformity assessment system (legislation, standard, certification procedure, rules) within the notified period.
- 9. Maintains a record of product complaints and makes it available to Sastek, takes appropriate measures to address product defects and errors affecting certification conformity and documents conformities. In this context; legal, commercial, organizational structure or property right, contact address, change of location, change of document scope, etc. inform Sastek without delay in fulfilling and maintaining the requirements of the product standard and other issues affecting the production of the product. In such a case, if the customer fails to inform Sastek, the process of suspension of the certificate is initiated.
- 10. Makes appropriate arrangements for auditors as well as accreditation auditors, etc., for the conduct of the audit
- 11. Assist the Lead auditor, auditor or Technical Expert in charge for certification promptly with the requested information.

# 19.2 Sastek's duties and responsibilities

1. Sastek maintains the information it obtains during the certification process within the scope of confidentiality and does not share it with third parties. Employees use the information obtained within the scope of certification activities only for the purposes set out in the contract. In addition, complaints, objections and applications received by Sastek regarding certification activities are notified to TÜRKAK, if necessary, in order to find a solution.



- 2. Sastek does not provide consultancy services for certification activities as required by TS EN ISO/IEC 17065 standard and its impartiality. In cases where it is mandatory to provide information to third parties in accordance with the legislation or when it is made available to the authorities, the customer is informed about the situation.
- 3. It is essential that Sastek provides conformity assessment services within the scope of the contract and at the prescribed level. In the event that the prescribed level is not achieved in the certification service activities provided, Sastek's responsibility is limited to the compensation of the service. In this context, Sastek has no monetary responsibility. In case of repetition of the same situation in the continuation of the activities, the customer may use the right to reduce the payment or terminate the contract.
- 4. Sastek has "Accreditation firms professional and liability insurance" against risks that may cause or result in damage within the scope of conformity assessment activities provided that it is verified. The scope and limits of Sastek's responsibilities regarding the subject matter are shown in the insurance policy.
- 5. In case of suspension or termination of Sastek's TS EN ISO / IEC 17065 accreditation, the damage that may occur in the certified product is covered not exceeding the certification service fee.
- 6. Sastek accepts no responsibility if the documents issued are not recognized by 3rd parties.

# 20. Relevant Documents/References Given in the relevant procedure.

## 21. Revision Tracking

No	Tarih	AÇIKLAMA
01	20.11.2019	The Framework Certification Program has been transformed into the Measuring Instruments Certification Program due to the narrowing of the scope.
0 2	21.01.2020	Follow-up supervision for closure purposes (Art:6.2.2)
03	27.02.2023	The document has been revised and reorganized.

APPROVAL: General Manager Denizhan ÖZER

Date:

Signature: