1.0 PURPOSE

The purpose of this procedure is to determine the principles for carrying out product conformity assessment activities according to the following modules defined according to Annex II of the regulation in accordance with the European Union legislation, taking into account the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9/3/2016 on Personal Protective Equipment.

2.0 SCOPE

This procedure covers the following modules defined according to Annex II of the regulation in accordance with European Union legislation, taking into account Regulation (EU) 2016/425 of the European Parliament and of the Council of 9/3/2016 on Personal Protective Equipment.

- 2016/425/EU Annex V Module B (Design type)
- 2016/425/EU Annex VII Module C2
- 2016/425/EU Annex VIII Module D

3.0 RESPONSIBILITIES

The Technical and Assurance Director is responsible for the approval of field inspectors, technical experts, assessors and decision makers and the Quality Manager, Notified Body Manager, Technical Expert, Assessor and Decision makers for the operation of this procedure.

4.0 DEFINITIONS

EU European Union,

Accreditation The formal acceptance by the national accreditation body that a conformity assessment body meets the requirements set by the relevant harmonised standards to perform a specific conformity assessment activity and, where applicable, the additional requirements stipulated in the relevant sectoral regulations,

Ministry Ministry of Family, Labour and Social Services,

Finished Product: PPE that does not need to undergo any further processing in order to be used and is ready for use,

"CE" marking: The mark indicating that the personal protective equipment by the manufacturer complies with all the relevant rules of the legislation prescribing the affixing of the "CEmark,

Distributor A natural or legal person other than the manufacturer and importer who has personal protective equipment on the market by taking part in the supply chain,

Recall Any measure aimed at returning personal protective equipment in the possession of the end user to the economic operator,

Observation: A situation that is observed during the audit and can be proved with objective evidence. Observations that may turn into nonconformities if no precautions are taken are included in this definition, and observations are stated in the audit report.

Economic operator Manufacturer, authorised representative, importer and distributor,

Manufacturer: A natural or legal person who manufactures personal protective equipment or has it designed or manufactured and markets it under its own name or trade mark,

Importer: A natural or legal person resident in Turkey who imports personal protective equipment from abroad and places it on the market,

Personal Protective Equipment (PPE);

1) Equipment designed and manufactured to be worn or held by persons for protection against one or more health and safety risks,

2) Replaceable parts of the equipment referred to in subparagraph (1) which are necessary for the protection function,

3) Fastening systems for the equipment referred to in subparagraph (1), which are not worn or held by persons, which are designed to connect the equipment to an external device or a suitable anchorage point, which are not permanently attached to a structure and which do not need to be fixed before use,

Commission European Commission,

Module: In accordance with the Regulation, each of the ways showing which conformity assessment process the product will be subjected to according to the risks it carries,

Placing on the market: The first time PPE is placed on the market,

Placing on the market: The provision of PPE to the market for distribution or use through a commercial activity, with or without remuneration,

Withdrawal from the market: Any activity aimed at preventing PPE in the supply chain from being placed on the market,

PMA: Special Material Assessment

Final Product: The last one supplied to the market from the PPEs within the scope of the same documents showing compliance with the relevant technical regulation,

Technical specification (Technical File): The document defining the technical requirements that PPE must fulfil,

Type: PPE representing the product planned to be produced

TURKAK Turkish Accreditation Agency,

USB Pruva : Software for managing conformity assessment processes

Conformity assessment: The process that shows whether PPE the essential health and safety requirements set out in this Regulation,

Conformity assessment body: The body that carries out conformity assessment procedures including calibration, testing, inspection and certification,

Harmonised standard: a European standard adopted at the request of the Commission for the purpose of implementing harmonised European Union legislation,

Authorised representative (COMPANY): A natural or legal person resident in Turkey who is authorised by the manufacturer under a written contract to fulfil certain obligations of the manufacturer under this Regulation on its behalf.

5.0 PROCEDURE

5.1 Application, Offer and Contract

5.1.1 COMPANY requests, taking into account the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9/3/2016 on Personal Protective Equipment, applications are received with the "*Notified Body Application Form*" for the activities covered by the European Union legislation. Applications are evaluated according to the "*Application Evaluation and Contract Procedure*" and the project is started after the relevant contracts are signed.

5.1.2 After the application is made, the scope of accreditation is evaluated by the Quality Manager or Customer Relations and Sales Specialist according to its compliance with the criteria required by the PPE regulation and TS EN ISO / IEC 17065 standard requirements, and if the evaluation result is appropriate, the suitability of the application with the "*Application Review Form*" is approved by the Notified with the form or USB Pruva software.

5.1.3 The application acceptance criteria to be considered at this stage are as follows:

- Name, registered trade name and contact details of the manufacturer,
- Name, registered trade name and contact details of the authorised representative, if any,

• Whether the applicant is a real manufacturer or not is checked with the Chamber of Industry Registry information, Chamber of Commerce registry information. If the application is from abroad, it is evaluated according to the legislation of that country. Support is received from the Integrity department in this regard.

• Which of the certification modules specified in the annexes of the PPE Regulation (EU) 2016/425 and which are within the scope of USB Certification's accreditation and whether the module qualification can be carried out by USB Certification in relation to the product,

• Whether it can be done by and/or

5.1.4 After being evaluated by the Customer Relations and Sales Specialist, it is approved by the Notified Body Manager in case of conformity and then its conformity or non-conformity is notified to the COMPANY by the Customer Relations and Sales Specialist.

5.1.5 The documents that must be attached to the application form are specified in the relevant application form. When the relevant documents are delivered to USB Certification, the documents are collected and followed up in the file opened by the Customer Relations Unit and a copy is kept electronically.

5.1.6 USB Certification verifies the information from the customer. The information provided for certification activities is carried out by performing the necessary measurements with the relevant devices and / or by taking copies of the necessary records and keeping them in the relevant file when the USB Certification field auditor / evaluator actually goes to the enterprise.

5.1.7 In cases where visual verification is required, the technical expert determines his/her observations in the relevant report.

5.1.8 If the application evaluation is positive, an offer is prepared in accordance with the "*Pricing Procedure*". With the submission and approval of the "*Certification Agreement and Offer Form"*, mutual agreement is reached on the date of initiation of the procedures and practices.

5.1.9 Before sending the *"Certification Contract and Offer Form"*, the tests that can be performed in accordance with the protection type are determined. In the form; it is stated that the tests will be performed by USB Certification or by which subcontractor laboratory.

5.1.10 Changes to the contract shall be notified by the Notified Body Manager to all personnel who will be affected.

5.1.11 If a laboratory other than USB Certification will be used for the product, the subcontractor laboratory is specified to the customer in the contract or its annex and approval is obtained. If it is done outside USB Certification, subcontractor selection is made according to the *"Outsourced Products and Services Procedure"*. All requests are put in writing and their compliance with TS EN ISO/IEC 17065 standard and related directives are reviewed (whether the laboratories can fulfil the request or not, etc.) and approved if applicable.

5.1.12 In case of any change in the request or the contract/protocol to be made, this change is made before the work is started. All records of the review of requests, offers and contracts (change records, assignment of the experiment to another subcontractor, change in the contract, etc.) kept as quality records according to the "*Records Control Procedure" and "Technical Records Guide"*. Changes in the contract that may be required after the start of the process are finalised in agreement with the COMPANY. If changes are required to be made to the contract after the work is completed, it is recorded.

5.1.13 The preliminary preparations to be made by the customer before the inspection (for situations requiring inspection) are specified in the *"Notified Body Application Form*

5.1.14 In all conformity assessment processes; If one or more non-conformities are detected by the Assessor and / or fail the tests, the certification process is terminated.

5.2 Conformity Assessment Programme

5.2.1.1 In order to establish the conformity assessment programme, Product Certification Programme types have been determined against the Conformity Assessment functions and activities in the Product Certification Programme and are given in the chart below.

5.2.1.2 Performance Monitoring The *"Notified Body Qualification Requirements and Authorisation Form*" is filled out by the Technical and Assurance Director for the Assessor/Decision Maker/Technical Expert who is successful in the audit and added as Assessor/Decision Maker/Technical Expert in the relevant module for PPE in the *"Personnel Competence Table*".

Conformity Assessment Functions and Activities in Product Certification Programme		*Product Certification Programme Types*		
		Annex-V (B)	ANNEX VII (C2)	ANNEX VIII (D)
1st Selection	Determination of Mandatory Documents (Application Form, Contract, Technical Expert Assignment)	✓	✓	✓
	Evaluation of the tests to be performed	✓	✓	✓
2.Determination of Properties	Inspection or Test	✓	✓	✓ (if required in QMS)
	Technical File Review	✓	✓	✓
	Evaluation of Services or Operations			✓
	Verification	✓	✓	✓
3. Review	Analysing the Evidence of Conformity Obtained	✓	✓	✓
4. Certification Decision	Issuance and maintenance of the certificate extension of the scope decision to suspend or withdraw the certificate	✓	✓	✓
5. Certification	Issuance of the Certificate	✓	✓	✓
	Granting the Right to Use Certificate and CE Marking		✓	✓
	Issuance of a Certificate for Quality Control of the Product			✓
	Issuance of Certificate for Product Type	✓	✓	✓
	Issuance of Certificate for Product Group Type	✓	✓	✓
6. Surveillance	Inspection or Testing of Samples Received from the Manufacturer	✓	✓	✓

	Quality System Based Surveillance Audit			✓
	Interim visits		✓	✓

5.3 Determination of Maximum Man/Day Duration for Product Certification Audits

5.3.1 Calculation

5.3.1.1 Decision *TURKAK R10.09 Guideline for Calculation of Audit Periods (Man/Day) for Accreditation Audits* and *IAF Mandatory Document Issue 3 (IAF MD5)* document are taken into consideration in determining audit man days.

5.3.1.2 The COMPANY in determining the audit period related to the audit of the customer (UDK) to be subjected to the accreditation audit on a man/day basis;

- The scope of the activity for which the application is made,
- Number of staff participating in conformity assessment studies (if Module D),
- Organisation structure,
- Addresses (locations) where the activities are carried out,
- The breadth and difficulty of the scope,
- In order to determine the competence and performance of the COMPANY, the issues of making observations by sampling in conformity assessment works or performing witness audits by giving priority to the critical ones of the certification and inspection type works carried out in the field are evaluated.

a. For Module B, the number of assessors/days is determined by the Notified Body Manager according to the examination difficulty of the product and the scope of the application.

b. For Module C2, the number of assessors/day is determined by the Notified Body Manager according to the amount of product production, production processes and scope of application.

c. When determining the total audit time for Module D, the following table is taken into account by considering the ISO/IEC 17021 standard.

Number of Employees	Field Audit (Auditor/Day) (Document review, preliminary preparation, field audit and reporting on quality management system)
1-10	2 (+-1)
11-20	3 (+-1)
20-	4 (+-1)

Factors Increasing the Audit Duration (Assessor/Day)

- Activities carried out in more than one branch/building and limited access and communication possibilities
- Audit work requiring translation into a foreign language
- Work to be carried out under high safety precautions
- Inspection in field conditions
- Work under the regulatory influence of official regulations
- Large number of client employees and/or wide scope to be audited Factors Reducing the

Audit Time (Evaluator/Day)

- The scope to be certified is also certified by another certification body
- Work carried out with few personnel in a small neighbourhood
- Maturity of the applicant organisation's management system

- The simplicity of the conformity assessment work within the scope to be certified and the ability of a large number of personnel to perform the same work
- Being certified according to another certification standard.

For Module D, the audit time (Assessor/ Day) determined in the table covers the auditors' file review, audit planning, necessary communication, audit and report writing.

The (Assessor/Day) times shown in the table do not include the time spent by Assessors/Field Supervisors/Technical Experts for transport. One (Assessor/Day) unit corresponds to a full working day of 8 hours. The number of Assessors/Days shall not be reduced by scheduling more than 8 hours of work in a day.

(Assessor / Day) unit durations shown in the table are given for initial certification audits. For surveillance audits, 50% of the periods given in Table 1 should not be exceeded within one year. The time allocated for surveillance audits is determined by taking into account the review of the organisation's activities at regular intervals, changes in the structure of the audited organisation, the maturity of the audited system.

Care is taken to ensure that the time allocated for recertification audits (Assessor / Day) does not exceed ¾ of the time used for the organisation's initial certification audit.

5.4 EU Type Examination Module (Annex V- Module B

The applications within the scope of this module are carried out in accordance with the rules of Module B (Annex V) Type Examination.

5.5 EU Type Examination Module (Annex VII- Module C2

The applications within the scope of this module are carried out in accordance with Module C2 (Annex VII) Type Examination rules.

5.6 EU Type Examination Module (Annex VIII- Module D

The applications within the scope of this module shall be carried out in accordance with the rules of Module D (Annex VIII) Type Examination.

5.7 Notification of Certified Products (Certificate Creation and Ministry Notification)

5.7.1 After the certification decision is made, USB Prospect Entry is made after the control of the Technical and Assurance Director.

5.7.2 The decision-maker enters the relevant information and a request for the creation of a document in the USB FTP system.

5.7.3 After approval, the Decision maker makes the final certification decision and a QR code is generated from the system. The QR code is added to the certificate and sent to the COMPANY.

5.7.4 Information on the published document is recorded by the Quality Manager in the *"Notified Body Customer List"* and the ministry is notified by a cover letter. The list of certified companies is updated by the Quality Manager every time a document is published. The originals of all published certificates are shared with the customer online. Upon customer request, they are sent by e-mail or cargo within 3 working days at the latest.

5.7.5 The document is published on https://www.usbcertification.com/ in an accessible way after filling in the relevant fields.

5.8 Use of the Certification Logo

5.8.1 USB Certification offers the Certification Logo to its customers on a licensed basis for tracking and exclusivity, the licensed logo cannot be directly attached to the manufactured product or used in a way that can be interpreted as product certification.

5.8.2 It is used by customers who have certificates related to the programmes accredited by USB Certification according to the *"Procedure for the Rules of Use of Documents and Logos"*. The USB Certification logo is available on USB Certification's website.

5.8.3 USB Certification licensed logos may be reproduced in monochrome to match the colours of company promotional literature or newspapers and magazines, but may not be reproduced in colour combinations other than those specified by USB Certification. The logo must also be clear and legible and must not be used in a misleading manner.

5.9 Complaint audits

5.9.1 USB Certification has the right to conduct additional audits in case of complaints, requests from official institutions or if deemed necessary as a result of risk analysis. It is also recorded with the contract made with the COMPANY. The scope and criteria of the audit are reviewed and determined by the Notified Body Manager and Assessors. This may be full, partial or only one process / section depending on the conditions.

5.9.2 This procedure is also in the normal audits of USB Certification.

5.10 Suspension of Certification

5.10.1 USB Certification reserves the right to suspend the Conformity Assessment Certificate for a certain period of time in the following cases.

- Cessation of the COMPANY certification scope activity due to various force majeure,
- continuous postponement of the surveillance audit programme without valid reason,
- By COMPANY request,
- Certification Certificate, USB Certification and/or TURKAK logos are used for misleading purposes or
- If any of the USB Certification certification rules General Conditions - 'Service Receiving Party' obligations clauses are violated and the problem is not resolved within the time frame specified by USB Certification, the COMPANY certificate is temporarily invalid as long as it is suspended.

5.10.2 The decision to suspend is ultimately taken by the Technical and Assurance Director. The suspension period varies between 1 and 6 months depending on the non-conformity.

5.10.3 After the suspension decision, an Assessor is appointed by the Technical and Assurance Director to follow the processes set out below:

- Follow-up of the processes carried out by the customer within the scope of the obligation to ensure that the document is not used falsely and misleadingly;
- Notification of the suspension decision to the customer and the relevant legal authorities;
- Notifying the COMPANY in writing of the correction of the conditions related to the suspension before the suspension is lifted
- At the end of the suspension period, a survey determine whether the requirements have been met;
- Notifying the COMPANY of the decision to lift the suspension if the activities carried out are deemed sufficient.
- If the activities carried out are insufficient, the decision of "Withdrawal of the Certificate" given by the Technical and Assurance Director is notified to the COMPANY in writing.

5.10.4 Any costs incurred by USB Certification during the suspension or lifting of the suspension will be borne by the COMPANY and the suspension will be published by USB Certification.

5.11 Withdrawal of the Certificate

5.11.1 USB Certification reserves the right to withdraw the certification certificate if

- As a result of inadequate measures taken by the COMPANY following
- Failure of the COMPANY to comply with the material obligations for certification
- Failure of the COMPANY to be present at the address specified on the document
- Change of legal entity of the COMPANY.

• In case it is detected that the COMPANY destroys the document and contract

• In the event that the Management System conformity of the COMPANY is completely lost in the audits carried out within the validity period of the certificate,

5.11.2 Following the withdrawal of the Certification certificate by USB Certification, the customer shall immediately stop the use of USB Certification and TURKAK logos on all written, stationery and promotional hand materials.

5.11.3 Certification Certificate must be returned to USB Certification within 30 days. USB Certification will keep all its legal rights confidential in case it is detected that the reference to the certification status of the COMPANY continues and the use of USB Certification and TURKAK logos in written, stationery and promotional hand materials continues. The COMPANY will be informed that the Certification Certificate has been withdrawn and will be given the right to appeal. However, no fee will be refunded and the withdrawal process will be published by USB Certification.

5.12 Cancellation of Certificate

The USB Certification certification certificate is cancelled at the request of the customer in the following cases:

- If the COMPANY does not want to renew its certificate or
- If the COMPANY leaves its business within the scope of the document or ceases its activities within the scope of certification.
- If the COMPANY wants to transfer to a certification body.

5.13 EU Declaration of Conformity

5.13.1 Applications within this scope are described in the "*Certification Procedure*". CE marking is used for the following modules.

- Annex V
- Annex VII
- Annex VIII

5.13.2 The EU Declaration of Conformity includes the following;

a. EU declaration of conformity (minimum qualification according to the Regulation)
b. Product model/product (product, type, group or serial number)
c. Name and address of the manufacturer and authorised representative, if any
d. This declaration of conformity the responsibility of the manufacturer. Company)
e. The subject of the declaration (a description of the product allowing its traceability; identification of the product Type, Type,
f. Technical specifications, Serial number, Ex coding)
g. The declaration that the relevant EU harmonisation legislation (regulation) is complied with,
h. References to the relevant harmonised standards and/or other technical requirements applicable to the declaration of conformity,
i. Where applicable, the notified body ... (name, identification registration number) ... (description of the modular system of application) and the number of the certificate issued
j. Additional information:
k. Authorised signatory or signatory on behalf of

the authorised signatory: (Place and date of

issue):

(Nameposition(signature):

5.14 Document Change

USB Certification follows the following path for changes to be made after the certification, certificate and/or examination report is published:

• A new certificate/examination report is issued stating the changes made. The documents shall refer to the previous document number.

• COMPANY is informed. If necessary, the COMPANY receiving service from USB Certification also writes a letter about changing the product label, informing its own customers that it sells the product and feedback the result to USB Certification.

• The amendments shall be notified to other notified bodies, TÜRKAK and the Ministry.

5.15 Information on Notified Body Identity

USB Certification fulfils the following obligations as a notified body.

• USB Certification keeps all necessary records of all transactions and documents issued by it and submits them to the examination of the Ministry when necessary.

• The Ministry is notified of all certification decisions regarding issued, cancelled and suspended certificates/licences.

• Notify the Ministry within 30 days at the latest of any structural changes that may affect the continuation of their activities within the scope of the procedures and authorisations determined.

• Notifies the Ministry within 15 days at the latest of any change in contact information, Takes all necessary measures to ensure that all producers benefit from the conformity assessment service on equal terms.

• It participates in all kinds of activities to increase coordination and co-operation both in Turkey and the EU.

• Participation in the activities of the Notified Body Coordination Group organised by the EU and defines the guidance documents to be issued from these activities in the Outsourced Document List.

• As a result of the conformity assessment activities to be carried out, to examine the objections and complaints that may arise in cases where the certification request for any product is rejected or an approval for the product is not granted or the certificate of a previously certified product is cancelled:

  • Detailed notification to the manufacturer or its authorised representative of the reasons for the decision to refuse or withdraw approval,

  • Notification to the manufacturer or its authorised representative of existing legal rights and the periods for exercising these rights,

  • By allowing the manufacturer or its authorised representative to appeal the decision, to ensure that this appeal is examined by a person or persons who have no prior relationship with the decision in question but who have sufficient knowledge and experience on the subject and can act independently,

  • It is obliged to notify the Ministry and other notified bodies of the information on rejected or withdrawn approvals.

5.16 2016/425 Clarification on the Application of PPE Regulation and Related Standards

5.16.1 In case need for clarification regarding the implementation of the EU Regulation and related standards, USB Certification uses the CIRCABc portal created by the EU Commission of which it is a member. Entry to this portal PPE (PPE Notified Bodies Group) documents called Clarification Sheets, which are published in the joint communication group of Notified Bodies working on the European Union PPE Regulation and which are the explanations made by the relevant Notified Bodies for the solutions of common problems encountered, are consulted. Here are the answers given by the relevant experts to the questions arising from the problems and hesitations encountered in the application of PPE standards and PPE Regulation since 1998. Horizontal and Vertical Group documents are examined.

5.16.2 However, during the evaluation of these answers, the identity of the persons who asked and answered the question and the organisations they work for are assessed. The Essential Health and Safety Requirements of these persons or organisations

It is necessary to evaluate the risk that the answers given with the idea that the subject or product being examined may be a party to the subject or product being examined may pose in order to ensure impartiality and objectivity in the explanation of the question.

5.16.3 For this purpose, in Article 6 of the ISO 17007 Standard, the organisations that give an opinion on the conformity assessment activity;

- Industrial organisations producing these products and their associations

- End user or Purchaser representatives

- Rule makers

- Representatives of Civil Society Organisations

- Accreditation Organisations

- Conformity assessment bodies

- It may be Insurance Organisations.

Therefore, in order for the information obtained here to be impartial and objective, not by interest groups;

- Accreditation organisations

- Rule Makers

- It must be evaluated by Conformity Assessment Bodies.

This has been taken into account in the USB Certification "*Impartiality and Conflict of Interest Risk Analysis*".

5.16.4 In addition, Blue Guide Information From European Union Institutions, Bodies, Offices And Agencies European Commission (COMMISSION NOTICE) The 'Blue Guide' on the implementation of EU products rules 2022 (Text with EEA relevance) is used and both the innovations and changes in conformity assessment issues and the requirements of this document regarding the ATEX Regulation are taken into consideration.

6.0 DOCUMENTS AND RECORDS

Document Number	Document Name and Description
UOF-NB-KKD-TR-4030	Notified Body Application Form
-	Blue Guide Information From European Union Institutions
UOF-NB-KKD-TR-4040	Application Review Form
UOP-NB-TR-4010	Remuneration Procedure
UOF-NB-TR-4050	Certification Agreement and Offer Form
QMS-QMS-P-TR-2010	Records Control Procedure
UAU-NB-KKD-F-TR-7050	Notified Body Qualification Requirements and Authorisation Form
UAU-NB-F-TR-7040	Personnel Competency Table
TURKAK R10.09	Guidance on Calculation of Audit Times (Man/Day) for Accreditation Audits
IAF MD5	IAF Mandatory Document Issue 3
UOP-NB-TR-4070	Procedure for the Rules of Use of Certificates and Logos
UOP-NB-TR-4040	Certification Procedure
UOP-LAB-TR-4270	Outsourced Products and Services Procedure

UOP-LAB-TR-4210	Technical Records Guide
QMS-QMS-F-TR-2230	Impartiality and Conflict of Interest Risk Analysis

Annex 1: Qualification Requirements for Evaluator/Technical Expert Team and Decision Makers

Mission	Learning	Training/Course	Experience	Additional requirements	Sustainability Requirements
Evaluator / Technical Expert	Graduates of Chemical, Mechanical, Textile, Industrial, Electrical Engineering and equivalent engineering and related undergraduate programmes	ISO 9001 Chief Auditor Training (preferably), ISO 19011 Training, PPE Regulation Training, Harmonised standard trainings	Minimum 1 Year Professional Experience	Technical Standard Information	Performance Evaluation, Surveillance, Witness Audit, Official Institution (TÜRKAK, Ministry, etc.) Audits during the year
Decision Maker	Graduates of Chemical, Mechanical, Textile, Industrial, Electrical Engineering and equivalent engineering and related undergraduate programmes	ISO 9001 Chief Auditor Training (preferably), ISO 19011 Training, PPE Regulation Training, Harmonised standard trainings	Minimum 3 Years Professional Experience	Technical Standard Information	Performance Evaluation, Surveillance, Witness Audit, Official Institution (TÜRKAK, Ministry, etc.) Audits during the year