





TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

Prepared by:	Reviewed by:	Approved by:
Eng. Ghassan M. Ramadan - Quality Manager 	Eng. Yasir Ali Manager- PS 	Eng. Shaheer Marath Regional manager- PS 

Revision History

SL #	Rev.	Date	Change Made by	Reason for change	Content of Change
1	0	15-08-2017	Dept	Introduction	NIL
2	1	21-11-2023	Dept	Audit Findings	Throughout the document
3	2	01-08-2024	Dept	Change to new control format	Throughout the document

1. Purpose & Scope:


This procedure aims to describe the steps adopted by TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING Quality for: Application For certification related to all the scopes TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING Submission Procedures. This procedure is applicable for both Full Quality Assurance and Products Certification. Those scopes of products covered in this procedure are as per TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING current Quality Manual.

2. Certification Body (Issuing TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING Certificates)

2.1. Chemical Sector:

- Cosmetics –accredited (system abbreviation (CAB))
- Detergents–accredited (system abbreviation (CAB))
- Perfumes –accredited (system abbreviation (CAB))
- Tobacco Products (Cigarettes, Mosel, Dokha) –accredited (system abbreviation (TBC))
- Labeling of Tobacco Products (Cigarettes, Moassel, Dokha, Cigars) –accredited (system abbreviation (TBC))
- Food Contact Materials (FCM's) –accredited (system abbreviation (FCM))
- Oxo- Biodegradation of Plastic Bags and other disposable plastic objects–accredited (system abbreviation (OBP))
- Petroleum Products –accredited (system abbreviation (PTM))
- Liquefied Petroleum GAS Products –accredited (system abbreviation (LPG))
- Retreaded Tires–accredited (system abbreviation (RTR))
- Paints – accredited (system abbreviation (PNT))
- All cosmetics products regulated by SFDA

2.2. Food:

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

Energy Drinks–accredited (system abbreviation (END))
Water–accredited (system abbreviation (WTR))
Organic Products–accredited (system abbreviation (ORG))
Honey Products – accredited (system abbreviation (HNY))
Milk & Dairy Products – under processing accreditation (system abbreviation (MLK))
Juices & Fruit Nectars – under processing accreditation (system abbreviation (JC))
All food products regulated by SFDA

2.3. Electrical Products:

Electrical and Gas Appliances–Under accreditation (system abbreviation (EGA))
Energy Efficiency Standardization and Labeling (EESL) Program–Under accreditation (system abbreviation (EGA))
Water Heater- accredited. (system abbreviation (WHT))
Elevators – accredited (system abbreviation (ELV))
Escalators – accredited (system abbreviation (ESC))
Scooter

2.4. Miscellaneous:

Speed limiters – accredited (system abbreviation (SPL))

Notified body for Ministry of Industry and Advanced Technology (MOIAT):

Same above scopes of products.

Certification Body (3rdParty CAB) authorized by Saudi Standards, Metrology & Quality Organization (SASO):

SASO Certification Process for regulated products

Notified body for Saudi Food and Drug Authority -SFDA Certificate of Conformity for Food and Cosmetic products


4. Responsibilities:

It is the responsibility of the Regional Manager, Quality Manager and PS Manager to ensure the appropriate implementation of this procedure. All departments managers also have immediate responsibility for the management of records relating to their activities.

5. Definitions:

- QM-Quality Manager
- QP-Quality Procedures
- QM-Quality Manual
- QMS-Quality Management System
- SOP-Standard Operating Procedure
- QML-Quality Master List
- QF-Quality Form

6. Requirements for certification:

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

The requirements against which the Products of a client are evaluated shall be those contained in specified schemes, applicable standards and other normative documents-ISO DOC, Explanations, clarifications. Furthermore, if TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING seeks collaboration with other organization to perform any related evaluation activity to certification, testing activities, it is done exclusively through accredited laboratories as per ISO 17025.

Clients seeking to be certified for any of their (Products or services or Full Quality Assurance) to UAE Schemes and applicable standards through TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING QUALITY are requested to implement relevant Quality System including documentation in a way to meet all requirements of this standard and all relevant specific standards depending on the nature of service (certified Product& Full Quality Assurance).

Where applicable, in case of a client newly operating, and seeking to be certified, Client is required to demonstrate more than 3 months compliance against the standard immediately preceding the date of audit performed by TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING Conformity Audit Body. This will prove the efficacy and sustainability of the implemented system. After which TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING will be contacted to decide for required audits and Certification.

Requirements varies depending on the scope of certified products; Details of the documents required for certification for each scope as per scheme owner requirements are detailed in the following Procedures:

A. SASO Certification Scheme:

TUVSUDPC-SOP-02A SASO Certification for Regulated Products

B. MOIAT Certification Scheme:

Refer Master List of internal documents TUVSUD-PS-GEN-REC-001

C. SFDA Certification Scheme


Refer Master List of internal documents TUVSUD-PS-GEN-REC-001

Generally, the requirements for certification are detailed as following:

7.1. Application for Certification (Application Form): Application to be filled by the client will contain all the necessary information needed by TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING for conducting the certification Process, such important information is:

- Type of Product to be certified: Product, Full Quality Assurance (Process) to identify the related scheme implemented by scheme owner.
- Relevant standard- or normative documents clients is seeking certification for.
- General information: Applicant Business activities & related business facilities & relationship between their facilities, in relevance to the certification scheme applied for information about outsourced Processes relevant to Product conformity.
- Any other information needed related to certification requirements.
- By signing the application form, the applicant and the manufacturer agrees to comply with these General Rules and with the Specific Product Standard for the product covered by Registration- CB Certification

7.2. Legal Agreements:

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

- Certification Agreement.
- Non-Disclosure Agreement.

7.3. Fees as detailed in TÜV SÜD service offer.

Please refer to Related Form below

- Self- assessment Checklists
- Application Forms
- Legal & Quality Documents-List of certification activities and requirements per certification Schemes
- Product Certification Schemes

Client seeking extension or renewal of Certification scope shall as well submit the application form specifying the extension or renewal of the Certification scope.

The Self- assessment checklist aligns all requirements of the specific standard to which client wishes to be certified and which must be submitted along with the application later.

Whenever applicable, additional Certification requirements per Certification schemes: Legal & Quality documents (such as Client Quality Manual) and supportive documents (records and checklists used by applicant), are to be attached to the Self- Assessment Checklist requirements and submitted along with the application as well.

7. Procedure of certification:


Although two types of certifications are applicable.

8.1 Full Quality Assurance Product Certification (Type Approval)

In addition to Product Certification Module H (Product certification for Hazardous Products which requires Full Quality Assurance audit), please refer to schedule of Fees (TUVSUD-PS-GEN-REC-046) for details.

7.1.1 Preparatory Steps:

- i. Application Form shall be submitted by applicant to TÜV SÜD MIDDLE EAST (submission can be done via TÜV SÜD MIDDLE EAST affordable communication methods (mail, emails, hard copy, website, E-System)
- ii. Application form through the emails ,mails and Hardcopies from the clients of TUV SUD Branches such as Saudi Arabia , TUV SUD PSB PTE LTD/Singapore ,TUV ITALIA SRL/MILANO and TUV SUD America will be send by the branch team to the Admins of TÜV SUD MIDDLE EAST Dubai Branch for the reveiw .Whether the application submitted only through the E-sytem /Website will be directly accepted by the TUV SUD MIDDLE EAST Dubai Team.
- iii. Administrative assistant/Operation coordinator will review it to check documents availability on a primary basis
- iv. Administrative assistant/ Operation coordinator will transfer the request to the Conformity Engineer by referring Competency Matrix- TUVSUD-PS-GEN-REC-068
- v. Define standards applicable and scope of Certification.
- vi. Define and Confirm TÜV SÜD capability of performing the requested scope of Certification with all needed tools (personnel and documents) this should be assured by TÜV SÜD prior to conduct the Certification Process. TÜV SÜD defines and check its capabilities and competence to perform the Certification scheme which TÜV SUD has no previous experience.
- vii. The conformity Engineer will contact the Client including the clients who submitted the application through TUV SUD Middle east Branches to Gather all information related to client and ensure they are sufficient for the certification Process.
- viii. The conformity Engineer Obtain Client agreement on certification scope and standards assuring full understanding of the certification Process.

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

- ix. Request obtaining all other necessary information to complete the Certification Process according to relevant Certification scheme.
- x. Administrative assistant/Operation coordinator Provide a quotation to the client; containing the scope of work and fees related to each step of the certification process.

7.1.2 Application Review

- i. Upon acceptance of quotation by client, he is requested to Sign the Certification agreement. The certification agreement to be signed before proceeding further for the application.
- ii. Application along with related supportive documents will be received by Engineer who shall perform the application review.
- iii. If found satisfactory the engineer will proceed with Application Evaluation, if not satisfactory application will be returned to client for completion till it is found accepted with all the required documents as per the Regulations of MOIAT, SASO and SFDA and the relevant Conformity Assessment instructions.
- iv. In case of a positive declaration of previous rejection of certification by an accredited certification body: lead auditor will identify areas of potential non-conformities and set exact points that will depend on in further investigation of these areas (including whether any area of Certification should be more addressed, or the points changes per standards to be more investigated to proof applicant completely removed previous non-conformities preventing certification).
- v. In case of positive declaration of previous successful certification by an accredited certification body's SÜD will consider this point included in changes affecting certification, please refer to TUVSUD-PS-GEN-SOP-016 Post certification procedures.

7.1.3 Application Evaluation

PRODUCT CERTIFICATION

- i. Conformity Officer (Evaluator or Auditor) shall perform conformity assessment steps (Evaluation) related to the certification scheme and conformity assessment instructions:
- ii. Detailed documents review for all the documents and evaluation of product the eligibility of the Product for certification to assure compliance according to applicable schemes and standards.
- iii. Document review includes the check up for Test Reports parameters and results.
- iv. Note: No of Samples to be selected for testing is defined by the specific technical requirements and as per scheme owner.

7.1.4 Review:

TUV SUD Middle East will assign at least one person to review all information and results related to evaluation the review will be carried out by a person who is not involved in the evaluation process.


Recommendations for a certification decision based on review will be documented, unless the review and certification decision are completely concurrent by the same person.

Evaluation Outcome results:

If evaluation is pending for missing or invalid documents or other needed information to complete evaluation; Additional Supportive Documents will be requested by Applicant.

Evaluation includes Product Safety Verification through test reports provided on all safety Test parameters requested by applicable scheme-standards, test reports shall be issued by 3rd party accredited Laboratory sub-contracted according to the approved Standards and applicable technical requirements.

If test reports are not complying with Standards; Conformity Officer- assessor requests rectification of the non-complying aspects, then based on applicant confirmation of rectification, Collection of samples will be done to conduct the same

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

laboratory tests again and for once.

Evaluation will be repeated upon applicant re-submission of needed documents-information.

7.1.5 Decision of Certification: Upon submission of this information, and as per the result of documents review and completing product evaluation process,

- i. **Recommendation of approval of Product certification:** Product evaluation shows full compliance with applicable schemes-standards:
 - Application is initially approved by Conformity engineer -Assessor
 - Recommendation for certification approval will be made by another engineer who is not involved in the evaluation process.
 - Certification decision will be done by Regional Manager
 - Granting the issuance of Certificate of conformity
 - Certified Products will be listed in TÜV SÜD Certified Products registry.
- ii. **Recommendation of rejection of Product certification:** Product evaluation shows non-compliance with applicable schemes-standards, due to any reason preventing product from Certification:
 - Application is declined by Conformity Officer- assessor.
 - Recommendation for certification rejection will be made by PS Manager
 - Rejection decision will be done by Regional Manager
 - TÜV SÜD will inform client by an Official rejection statement (Letter of certification Status) by e-mail stating the reason of rejection.

8.2 Full Quality Assurance

Pre- audit (optional)

Pre- audit is an optional step chosen by applicant, its Objective is to assist applicant to determine that Quality System adopted meets requirements of Certification scheme and applicable standards, and it grants efficacy and sustainability for his operations related to the Product-service applicant wish to certify

Pre- audit is conducted once Fees are paid by applicant and received by TUV SUD.

Steps applicable on pre- audit like an official audit are: Preparatory steps, application review, application evaluation except that it is not mandatory for client to reply the evaluation report and close his NCs, unless he would like to continue and close his non- conformities.

Pre- audit Process is conducted at TÜV SÜD offices or on actual site depending on the individual case in hand.

Upon performing the Pre- audit, audit team leader will issue the TUVSUD-PS-GEN-REC-014 Evaluation Report.


The Pre- audit Report will give the result whether the applicant is eligible to move forward to the next step of evaluation (Actual on-site audit) or there are discrepancies and major non-conformities.

The Pre- audit Report will be sent from lead auditor (audit team leader) to PS Manager for his review and approval, and then sent to applicant. Here the evaluation ends and there is no proceeding to certification decision.

Pre- audit Evaluation Report to be sent by e-mail or any other suitable method, during which applicant to be informed of all the discrepancies and non-conformities that have been encountered and pointed out, to be addressed and rectified prior to the actual on-site audit.

In case interested in continuing the Certification Process, Applicant will be requested to confirm proceeding with the Certification process (actual on-site audit)

8.2.1 Actual on-site audit

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

- i. **Audit Preparation:** preparation of the audit starts to be done by TÜV SÜD as following:
- If pre- audit exists, after applicant’s assurance that he rectified all discrepancies available in the Pre- audit Report, actual audit start.
 - PS Manager assigns the auditor(s), including Lead Auditor and rest of Audit Team.
 - Criteria of Audit Team selection, as following: Audit team shall consist of at least two personnel covering below roles, Audit Team Members shall be selected to be competent and to cover the scope of category and consist of the following roles:
 - **Lead Auditor**
 - **Auditor**
 - **Technical Expert**
 - Additionally, and optionally and depending on each case, other roles can be included in audit team if needed as following:
 - **Translator.**
 - **Observer.**
 - **Witnessing auditor.**
 - Lead Auditor (audit team leader) shall perform conformity assessment steps (Evaluation) related to the certification scheme to decide on the nature of Stage I and Stage II:
 - Detailed documents review for all the documents to primarily verify compliance according to applicable schemes and standards.
 - Document review includes the check up for Test Reports parameters and results
 - Audit team leader to prepare audit duration plan based on applicable standards then finalize primary audit schedule.
 - Where Stage I audit has not been performed on-site, the duration of Stage I audit may not exceed 20% of the total audit time. Where it covers an on-site work, duration of the Stage I audit may not exceed 30% of the total audit duration.
 - Whenever Stage I and II will be performed on site, a separate audit schedule will be designated for Stage I and Stage II).
 - After which, administrative assistant will be responsible for:
 - Identifying audit location and related suitable logistics tools that should be available.
 - No Conflict of Interest against any of the suggested audit team members.
 - Share by e-mail or any other accessible documented method the primary audit schedule TUVSUD-PS-GEN-REC-013 for applicant approval and signature, or for further advice about the dates audit to reach a mutually agreed schedule.
 - Send applicant the invoice for actual on-site audit Fees, containing Terms& Conditions of Invoice of payment as per TÜV SÜD Policy:
 - Upon Applicant review, approval, and signature, administrative assistant will request applicant to send back the audit schedule form to proceed with the actual on-site Audit.

Note: For one specific audit, the Same personnel can perform the Pre- audit, and perform actual on-site audit, as he is more aware about applicant specifications and previous discrepancies, and this will lead to a continuous convenient performance of the Certification Process.

However, to assure no risk of no conflict, for Surveillance and renewal of Certification, TÜV SÜD assigns a new different personnel-Lead auditor not previously related to the Pre- audit- and initial Audit step.

ii. **Conduct of Audit:**


Audit procedures are applicable on all different type of Certification including New Certification, Surveillance, and Re-Certification.

Stages of Audits: Audit includes a 2-stage process:

Stage I Audit: The purpose of the Stage I audit is to evaluate applicant location and site-specific conditions and to determine preparedness for the Stage II audit.

During Stage I audit, audit team will check:

Applicant’s documents submitted along with the application of certification such as company manual, system level procedures, product specifications, other certificates.

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

Applicant’s understanding and implementation of the standard and related statutory, regulatory, and compliance issues
Verification of scope and other relevant information needed for certification.
Applicant management system and various mechanisms are functioning properly as per the applicable standards applied for certification.

The audit will identify any areas of concern that could become nonconformities. I communicates with any concern that prevents to proceed with

Stage II Audit:

At on-site Stage II audit, TÜV SÜD audit team will conduct interviews, examine records& documents, and observe the company’s activities.

The Stage II audit determines if the company has successfully documented and implemented all the requirements of the specified standard. This is accomplished via an in-depth review of manuals and procedures and the confirmation of their implementation. The audit also verifies conformance to the identified standard.


This audit also reviews and clarifies any areas of concern identified in Stage I, and Pre- Audit if applicable, Nonconformities.

If samples to be taken for testing purposes, No of Samples to be selected for testing is defined by the specific technical requirements and as per scheme owner. Furthermore, sample request form (TUVSUD-PS-GEN-REC-015) should be filled in on three copies; one copy to accompany the sample and sent to the accredited laboratory selected by client, the other copy to be kept with client for his reference, the last copy will be kept with TÜV SÜD file also for TÜV SÜD future reference.

8.2.2 Application Evaluation Outcome:

Nonconformity Reports (NCRs) along with all related assessment checklists of the applicable standards will be documented and identified as major or minor:

- Major non-conformities:
 - A major nonconformity is the absence or total breakdown of a system to meet a clause or sub-clause of a standard.
 - Many minor nonconformities against one clause or sub-clause can represent a total breakdown of the system and thus be considered a major nonconformity.
 - A situation that raises significant doubt about the ability of the applicant’s management system to achieve its intended outputs is also a major nonconformity.
 - A major nonconformity may require a separate re- audit of the applicable clause or sub clause before the applicant can be certified.
- Minor nonconformities:
 - Minor nonconformity might be a procedure that is not comprehensive enough, a person who did not follow the procedure, or a lack of a required record.
 - A minor nonconformity will generally be addressed by applicant submitting a response to the Lead Auditor before he can be certified. Depending on the standard, the corrective action for a minor nonconformity may not necessarily be closed prior to certification.
- A written audit report, containing any nonconformity, is issued after the audit, and assessment checklists related to each specific applicable standard to be filled with remarks whether applicant is complying with each clause or not.
- Although TÜV SÜD is constrained from consulting, and therefore cannot advise the applicant on how to react to a nonconformity, TÜV SÜD auditors are often able to offer a range of examples of actions that would meet the requirements of the standard, or examples of compliant (and nonproprietary) systems from experience.
- TÜV Sud provide resources to applicant to better understand appropriate responses to non-conformances and root cause analysis.

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

- Because only the applicant knows what is right for his business, TÜV SÜD auditors cannot say what solutions will work best within his company. He must determine his own nonconformity resolutions. The applicant may call TÜV SÜD for assistance if he encountered difficulties.
- Corrective Action (if needed): After the Stage II audit, nonconformities (NCRs) will be documented and identified as either major or minor then communicates to applicant via TUVSUD-PS-GEN-REC-014 Evaluation Report, discussing the same with him during the closing meeting to ensure applicant recognizes the non-conformities and undertake to make the necessary corrective actions within the agreed time frame.
- If nonconformities are found which cannot be corrected electronically and send back to TUV SUD, an onsite complementary audit might be needed to be scheduled to verify the implementation of the action(s) to resolve the nonconformities. The scope of the audit is limited to the clause or sub clause where major nonconformities were found. Non-conformances will need to be resolved in a timely fashion as per TUV SUD’s Certification Regulations. Other than that, client replies (root cause analysis, corrective action plan) filled in evaluation report, and actual corrective actions for non-conformities including supportive documents can be received via any accessible means by TÜV SÜD (email, hardcopies, E System, etc....)

8.2.3 Decision of Certification: Please refer to TUVSUD-PS-GEN-SOP-016 Post certification procedures- Other scopes.

8.2.4 First Certification Audit:

Certification Audit takes place at the Company’s headquarters location and based on the Audit Schedule, at a sampling of other non-headquarter locations beginning with the most significantly sized ones will be considered as well. Processes and activities carried out by the Company, within the scope of Certification schemes, and that most significantly affect the Quality of the company’s Product or service shall be included in the Certification Audit. Where Processes and activities relate to Projects, a sufficient number of Projects, or sampled sections of Projects, shall be audited to enable a decision to be made relating to compliance or non-compliance to the audit criteria. Records reviewed in the audit should also cover both current and closed Projects. Companies shall have approximately 3 months of Project records including completed Projects to undergo a Certification Audit. There shall be adequate documentation to demonstrate the sustainability of the company’s Quality System.

8.2.5 Surveillance Audits:

Please refer to TUVSUD-PS-GEN-SOP-016 Post certification procedures –Other scopes.

Re-Certification Audits:


Please refer to TUVSUD-PS-GEN-SOP-016Post certification procedures – Other scopes.

8.2.6 Justification of Certification Decision:

i. Review

In Certification, as it is crucial to differentiate the roles of evaluators and certifiers to be able to respect and meet the 4-eyes principle. The final recommendation (certification Review) and approval of audit result (Certification Decision) will be done by personnel who was not involved in the audit Process and who will review the audit result then issue the recommendation for Certification.

Done by	Decision	Justification
----------------	-----------------	----------------------

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

Audit Team Leader (Lead Auditor)	Application Evaluation	1. Product Certification: Approved when: A) 100% of points highlighted in assessment checklist per relevant UAE scheme is complying. b) Lab test findings are satisfactory either during the corrective actions 2. Full Quality Assurance: Approved when: a) 100% of major non- conformities highlighted in Evaluation report is rectified by corrective actions with supporting evidence of these actions before approval is granted and certificate is issued. Please refer to Notice Period for suspension and withdrawal and decline certification in procedure: TUVSUD-PS-GEN-SOP-016 -Post Certification Procedures (COC Issuance Surveillance and Recertification) b)100% of Minor non- conformities highlighted in evaluation report is rectified by corrective actions with supporting evidence of these actions (implemented either prior to approval is granted and certificate is issued, or after approval is granted by providing a detailed time lined action plan to eliminate the non-conformities) c) Lab test findings are satisfactory either during the certification or during the corrective actions
PS Manager (or delegate) (4 eyes principle policy)	Certification Review (Final Recommendation)	
ALL Scopes Regional Manager	Certification Decision	

Impact on TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING System as notified body for MOIAT, SFDA and as authorized certification body (3rd Party CAB) for SASO

As per the current portfolio of Products subject for Certification in TÜV SÜD MIDDLE EAST LLC, the same certification System used by TÜV SÜD is applicable on the scopes as TÜV SÜD Certification body, MOIAT Notification Body, SFDA Notification body, SASO 3rd Party CAB), however the forms used might varies as following:

Certification Body (Issuing TÜV SÜD Certificates):

All procedures implemented in the system are applicable, all documents available the system are applicable.

Notified body for Ministry of Industry and Advanced Technology (MOIAT)- (Issuing MOIAT Certificate of Conformity and Emirates Quality Mark:

All procedures implemented in the system are applicable, all documents available the system are applicable to be used, Expect the following documents should be replaced with MOIAT Forms:


Certificate template (all certificates templates below) to be replaced with (Certificate of conformity) For Emirates Quality Mark and Certificate of conformity.

Declaration of conformity (No equivalent for this form available in TÜV SÜD system).

Certification Body (3rdParty CAB) authorized by Saudi Standards, Metrology & Quality Organization (SASO)- (Issuing SASO Certificate of Conformity and Saudi Quality Mark):

All procedures implemented in the system are applicable, all documents available the system are applicable to be used, Expect the following documents should be replaced with SASO Forms:

- Certificate template (all certificates templates below) to be replaced with (Certificate of conformity) For SASO Quality Mark
- Application Form to be replaced with SASO Form (نموذج طلب الحصول على الترخيص باستعمال علامة الجودة)

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

- Evaluation Report (TUVSUD-PS-GEN-REC-014) to be replaced with SASO Form (NON- Conformity Report QMS– F –10 - 58 (تقرير حالات عدم المطابقة) and (Evaluation and SASO Mark licensing report (تقرير التدقيق والترخيص باستعمال علامة الجودة
- Sample Request Form (TUVSUD-PS-GEN-REC-015) to be replaced with SASO Form (Samples to transfer to lab (إحالة عينات للمختبر (محضر سحب عينات (Sample Withdrawal Form
- Application Review Form (No equivalent for this form available in TÜV SÜD system) (نموذج دراسة طلب الحصول على ترخيص باستعمال علامة الجودة
- Declaration of conformity (No equivalent for this form available in TÜV SÜD system).
- Opening and Closing meeting will be replaced with the SASO Form (Attendees List (فائمة الحضور
- Audit Schedule Form (TUVSUD-PS-GEN-REC-013) will be replaced with SASO Form (Audit informing application (مخطط التدقيق المبدئي (نموذج ابلاغ المنشأة بموعد تنفيذ التدقيق وكذلك اعضاء فريق التدقيق

10. Notified body for Saudi Food and Drug Authority-SFDA Certificate of Conformity for Food and Cosmetic products

- Certificate template (all certificate templates below) to be replaced with (Certificate of conformity) For SFDA Food products, and FASEH Platform for Cosmetics products.
- Application Form to be replaced with Application form for SFDA Certificate of conformity (TUVSUD-SE-SFDA-REC-05 Request form- SFDA certification)
- Audit forms to be replaced with SFDA inspection checklist (TUVSUD-SE-SFDA-REC-10)

11. Related Forms:


i. Specific Forms

All related specific forms (SOP and Records are indicated in the Quality Master List (QML) TUVSUD-PS-GEN-REC-001).

ii. General Forms:

Other Agreements, SOPs, Records related to the SOP 18 as follows:

Quality Master List	TUVSUD-PS-GEN-REC-001
Evaluation Report	TUVSUD-PS-GEN-REC-014
Audit Schedule Form	TUVSUD-PS-GEN-REC-013
Post certification Procedures (COC issuance, Surveillance and re-certification)- all scopes	TUVSUD-PS-GEN-SOP-016
Audit Planning Procedure (Preparation, stage I, Stage II, Audit Realization)	TUVSUDPC-SOP-04
Sample Request Form	TUVSUD-PS-GEN-REC-015
Schedule of Fees	TUVSUD-PS-GEN-REC-046
Opening-Closing Meeting	TUVSUD-PS-GEN-REC-041
Certification Agreement	TUVSUD-ME-GEN-AGR-003 TUVSUD-SE-GEN-AGR-004
NDA-TÜV SÜD MIDDLE EAST LLC-client-Contractor	TUVSUD-PS-GEN-AGR-002
SASO Certificate for Regulated products	TUVSUD-SE-SASO-SOP-002
SFDA Certification Procedure	TUVSUD-SE-SFDA-SOP-78
Request form- SFDA certification	TUVSUD-SE-SFDA-REC-05
SFDA inspection checklist	TUVSUD-SE-SFDA-REC-10
MOIAT Declaration of conformity	
SASO Quality Mark Certificate	
SASO Mark Application (نموذج طلب الحصول على الترخيص باستعمال علامة الجودة)	

TUVSUD-PS-GEN-SOP-015	Rev. No.: 06	Revision Date: 01-08-2024	Initial Date: 15-08-2017
TITLE:	Pre-Certification Procedures- Handling Applications from Submission until Issuance of COC – Full Quality Assurance & Products		

SASO Form (NON- Conformity Report QMS– F –10 - 58 (تقرير حالات عدم المطابقة 58 - 10 - F QMS- SASO Report Non-Conformity) and (Evaluation and SASO Mark licensing report (تقرير التدقيق والترخيص باستعمال علامة الجودة)	
SASO Form (Samples to transfer to lab (إحالة عينات للمختبر) (Sample Withdrawal Form (محضر سحب عينات)	
Application Review Form (نموذج دراسة طلب الحصول على ترخيص باستعمال علامة الجودة)	
SASO Declaration of conformity	
SASO Form (Attendees List (قائمة الحضور)	
SASO Form (Audit informing application (نموذج إبلاغ المنشأة بموعد تنفيذ التدقيق وكذلك مخطط التدقيق المبدئي) and (Initial Audit Schedule (اعضاء فريق التدقيق)	

12. References

- ISO/IEC 17065, Conformity Assessment - Requirements for bodies certifying Products, Processes and services.
- ISO/IEC 17021, Conformity Assessment — Requirements for bodies Providing audit and Certification of management systems.
- GAC Document: FAD- 4.0: Supplementary accreditation requirements for Product Certification Bodies.
- IAF Mandatory Document: Determination of Audit Time of Quality and Environmental Management System.
- ISO/IEC 17000, Conformity Assessment — Vocabulary and general principles.
- ISO/IEC 17020, Conformity Assessment— Requirements for the operation of various types of bodies performing inspection.
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.
- ISO 17067, in combination with ISO Guide 28 and ISO Guide 53
- ISO/IEC 17030, Conformity Assessment — General requirements for third-party marks of conformity.
- ISO Guide 23:1982 Methods of indicating conformity with Standards for third-Party certification Systems
- ISO Guide 27:1983 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
- General Requirements for Notified Bodies issued by Emirates Authority for Standardization and Metrology (MOIAT).
- Decree n° 6386 issued by the Trade and Industry Ministry of Saudi Arabia (MOCI), dated the 4th of August 2004
- ISO/IEC TR 17026:2015 Conformity Assessment -- Example of a certification scheme for tangible products (Type 5 Product Certification Scheme).
- TÜV SÜD MIDDLE EAST L.L.C/ TÜV SÜD SAFETY ENGINEERING Manual TUVSUD-PS-GEN-QM-001
- All controlled QMS records-Please refer to TUVSUD-PS-GEN-REC-001 Quality Master List.