PRODUCT CERTIFICATION SCHEME FOR TOBACCO PRODUCTS

1. Objective:

This procedure describes the criteria implemented by RACS as Notified Body of Emirates Authority of Standardization and Metrology (ESMA) to assure that **Tobacco** products intended for certification with ESMA are complying the relevant mandatory schemes and applicable standards.
Furthermore, this document identifies the steps taken by RACS Clients (Manufacturers, Traders, importers, retailers, Business owners or any other client) to get their products/processes certified prior to its commercializing in UAE market, and registered by through RACS Quality certificates issuing services as ESMA Notified Body by issuing certificates of conformity in accordance with ESMA Regulations:

2. Definitions:

- **ESMA**: Emirates Authority for Standardization and Metrology.
- **RACS**: RACS Quality certificates issuing services
- **Scheme:** Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply.
- **Certification:** Third-party attestation related to products, processes, systems or persons.
- **Notified Body**: a conformity assessment body designated by ESMA to conduct conformity assessment process on products and processes in accordance with related schemes/standards/regulations mandated by ESMA.
- **Conformity Certificate**: Formal document issued by RACS as notified body under approval of ESMA stating that certification is being granted for the product/process in accordance with applicable scheme/standards as per ESMA Requirements.

3. Responsibility:

It is the responsibility of RACS as ESMA Notified Body to establish and maintain the appropriate system to satisfy both ESMA and clients requirements in accordance to the notification system mandated by ESMA
It is the responsibility of ESMA clients and RACS clients to provide all needed requirements as per ESMA Notification system to ensure their products compliance to the applicable schemes and standards.

4. Introduction about RACS Notified Body to provide Certification:

RACS is an accredited certification body & ESMA approved notified Body under its notification system mandated by UAE decree No (35) Of the year 2015 & UAE Cabinet Resolution No (36).
RACS is an authorized conformity assessment body by ESMA that it is technically competent to perform the specific tasks of certification to ESMA clients.

5. Service Type:

As per Scheme owner rules, RACS certifies Tobacco Products and issues Certificate of conformity under:

- **Emirates Conformity Assessment Scheme (ECAS)**: ECAS is a Product Certification Scheme being implemented by the (ESMA) as mandated by the Federal Law 28 of 2001.

Issuance of certificate of conformity by RACS as ESMA's Notified Body assures the compliance of products/production process with the requirements of the approved schemes, standards and others specified in the technical regulation by Emirates Authority for Standardization and Metrology (ESMA).

6. Scope of certified products by RACS –ESMA Notified Body:

This document cover Tobacco products with below details of Sector, scope of certified products, products categories, and applicable type of certification:

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Sector (Product Group)	Scope of Certification (Scope of Products)	Product categories	Type of Certification
CHEMICAL	Tobacco Products	1. Cigarettes-Label Assessment	1. Product Certification -Type Approval (ECAS)- (Both Label and Product)
		2. Moassel-Label Assessment	
		3. Cigar-Label Assessment	
		4, Dokha-Label Assessment	
		5. Cigarettes-Product Assessment	
		6. Moassel-Product Assessment	
		7. Dokha-Product Assessment	

7. Mandatory Schemes and Applicable Standards:

Scheme applicable is the Gulf Technical Regulations to control tobacco Products (Cigarettes, Moassel, Dokha). If needed, Client refers to RACS to identify applicable Scheme and Standards.
RACS Staff to refer to RACS/REC/79 Scope of Certified Products by RACS to identify Certification applicable schemes and standards.

8. Requirements for Certification:

Requirements varies depending on the scope of certified products; Details of the documents required for certification for the scope of Tobacco Product as per ESMA requirements are detailed as following:

8.1. **Application for Certification (Application Form):** Application to be filled by the client will contain all the necessary information needed by RACS Quality for conducting the certification Process, such important information is:

- Type of Product to be certified: Product, facility (Process) to identify the related scheme implemented by ESMA.
- 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

Application form also contain Self-assessment checklist which aligns all requirements of the specific standard to which client wishes to be certified and which must be submitted along with the application), as following:

Product Certificate:

- Application (Online/ Manual)
- Declaration of Conformity by the Applicant on the Product(s) for Registration using the Applicant's Official Letterhead.
- Valid Industry/Trade License (For Companies within UAE).
- Test Report from accredited and ESMA approved lab as per the requirement of UAE.S GSO 597
- Test Report for the maximum limit of pesticide residues (in ppm) as per the requirement of UAE.S GSO 597
- Declaration of Conformity by the Manufacture on the additives content in the tobacco used for manufacturing cigarettes.
- Product Samples to be collected for Cigarettes Testing
- ESMA Approved Artwork (Product Labels) as per UAE.S GSO 246

- Product Certificate: Certificate for Labeling of Tobacco Products as per UAE.S GSO 246

8.2. **Legal Agreements:**
- Certification Agreement:
- Non-Disclosure Agreement

8.3. **Fees** as detailed in RACS Schedule of Fees (RACS/REC/46)

9. Certification Procedures:

Based on its role as ESMA Notified body, Procedure will be performed as following:

9.1. Preparatory Steps:

Based on its role as ESMA Notified body, Procedure will be performed as following:

9.2. Preparatory Steps:

9.2.1. Application Form shall be submitted by applicant to RACS, submission can be done via RACS affordable communication methods (mail, emails, hard copy, website, E-System)

9.2.2. Sales and Marketing Executives/Administrative assistant will review it to check documents availability on a primary basis

9.2.3. A quotation will be sent to applicant by Head of Sales and Marketing; containing the scope of certification and fees related to each step of the certification process.

9.2.4. Payment shall be done by applicant.

9.3. Application Review

9.3.1. Upon acceptance of quotation by client, he is requested to sign the General Conditions for Certification Services.

9.3.2. Application along with related supportive documents will be received by RACS Conformity Manager who shall assign one of RACS technical team members (Conformity Officer- (Evaluator or Auditor)).

9.4. Application Evaluation

9.4.1. Conformity Officer (Evaluator or Auditor) shall perform conformity assessment (Evaluation) steps related to the certification scheme (Product Certificate):

Product Certificate:

- Detailed documents review for all the documents
- Document review includes the check up for Test Reports parameters and results, done by 3rd party Laboratory according to the specific technical regulations and applicable standards.
- Evaluation of product the eligibility of the Product for certification to assure compliance according to applicable schemes and standards

Note: No of Samples to be selected for testing is defined by the specific technical requirements and as per scheme owner

9.4.2. 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 laboratory tests again and for once.
- Evaluation will be repeated upon applicant re-submission of needed documents/information.

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

9.5.1. Recommendation of approval of Product certification: Product evaluation shows full compliance with applicable schemes/standards:
- Application is initially approved by Conformity Officer/Assessor
- Recommendation for certification approval will be made by Conformity Manager
- Certification decision will be done by Decision Committee
- Granting the issuance of Certificate of conformity, recognized by ESMA
- Certified Products will be listed in RACS Certified Products registry.

9.5.2. 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 Conformity Manager
- Rejection decision will be done by Decision Committee
- RACS will inform client by an Official rejection statement (Letter of certification Status) by e-mail stating the reason of rejection.

Please refer to Available on RACS Website→Publicly available information→ RACS Notified Body →Required Docs→

- **TBC/REC/03**: Legal & Quality Documents-List of certification requirements per UAE Scheme – Labeling of Tobacco Products (Cigarettes, Moassel, Dokha, Cigars) &Tobacco Products- (Cigarettes, Moassel, Dokha).
- **TBC/REC/02**: Application Form: Tobacco Products (Cigarettes, Moassel, Dokha) & Labelling of Tobacco Products (Cigarettes, Moassel, Dokha, Cigars).
- **RACS/Ag/01**: Certification Agreement/RACS Quality - Client
- **RACS/Ag/03**: NDA/RACS Quality - Client/Subcontractor
- **RACS/Ag/10:** General Conditions for Certification Services

Notes for clients:

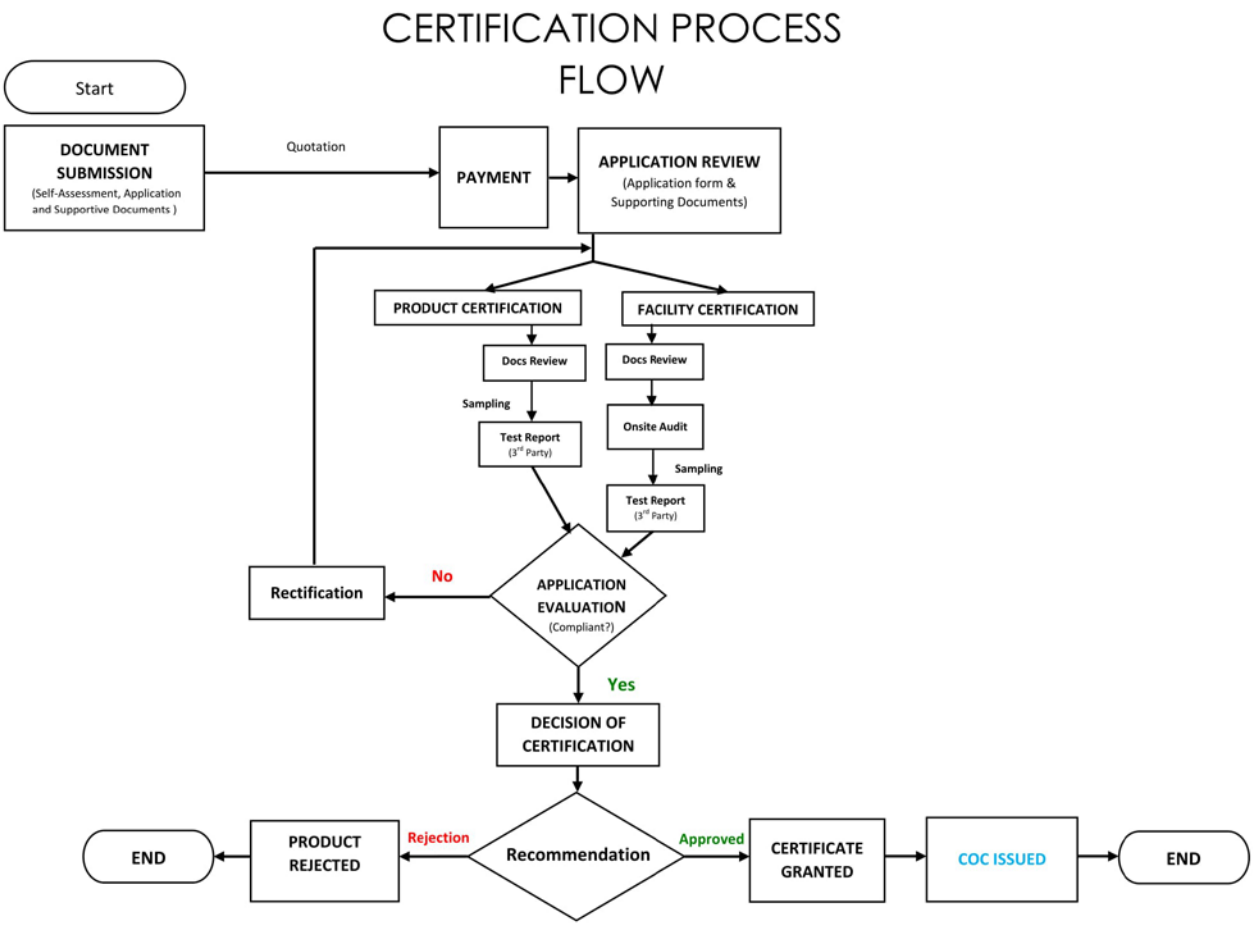
- For some scopes where it is required to have a quality system available, clients seeking to be certified for any of their (Products or services or facility/Process) to UAE Schemes and applicable standards through RACS are requested to implement relevant Quality System including documentation in a way to meet all requirements of this standard and all relevant specific standards depending on the nature of service (certified Product& Process).
- 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 the Pre-Assessment performed by RACS. This will prove the efficacy and sustainability of the implemented system. After which RACS will be contacted to decide for required audits and Certification.
- Client seeking extension or renewal of Certification scope shall as well submit the Application form specifying the extension or renewal of the Certification scope.
- 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 Application form.

10. Renewal:

Product Certificate:

- Validity of certificate is one year,
- COC should be renewed 2 months prior expiry.

11. Process Map:



12. Market Monitoring:

RACS Will be conducting Market Surveillance campaigns in the local markets to assure continuous compliance of certified products and inform Scheme owner on immediate basis on the non-conformity products to take the appropriate action.

13. Related Forms:

Listed Agreements, SOPs, Records related to the **SOP29** as follows:

General Forms:

TITLE OF DOCUMENT	IDENTIFICATION
Quality Master List	RACS/REC/01
Certification Agreement/ RACS Quality- Client	RACS/AG/01
NDA/RACS Quality - Client/Subcontractor	RACS/AG/03
Scope of Certified Products	RACS/REC/79

Schedule of Fees	RACS/REC/46

Specific Records related to the Scope:

UAE.S GSO ISO 10185 :2007-Tobacco and Tobacco Products Vocabulary	TBC/REC/01
Application Form	TBC/REC/02
Legal & Quality Documents-List of certification requirements per UAE Scheme –Tobacco Products	TBC/REC/03
Assessment Checklist- UAE.S/GSO 1415 :2011 Almeassel tobacco	TBC/REC/04
Assessment Checklist- UAE S. GSO 597:2009 Cigarettes	TBC/REC/05
Assessment Checklist- GSO 05/CD/246:2011 Packaging and Labeling for Tobacco	TBC/REC/07
TOBACCO - Tobacco Product Certificate Template	TBC/REC/09
Assessment Checklist- UAE S. GSO 2050:2010 for Tobacco Pipe (Dokha)	TBC/REC/10

14. References:

General Requirements for Notified Bodies –ESMA Document.
Requirements for Registration –ESMA Documents-Available in ESMA website and RACS website and upon request by RACS Staff.

- 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.
- ISO 9001:2015 Quality Management Systems
- GAC Document: FAD- 4.0: Supplementary accreditation requirements for Product Certification Bodies.
- R307: General Requirements Accreditation of ISO /IEC 17065 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.
- ISO17067, 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 (ESMA).
- RACS Quality Manual RACS/QM/01
- All controlled QMS records-Please refer to RACS/REC/01-Quality Master List.