PRODUCT CERTIFICATION SCHEME FOR E-CIGARETTE 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 **E-Cigarette** 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 the 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 client's 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 and ESMA approved notified Body under its notification system mandated by UAE Decree No. (35) of the year 2015 and 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 E-Cigarette Products and issues Certificate of conformity under:

Product Certification: Product Certification is an either a Product Certification Scheme being implemented by (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 certifies Chemical/Electrical-**E-Cigarettes (Product/Label/Device)** 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/Electrical	E-Cigarettes Label, E-Cigarettes Products, E-Cigarettes Device	1. **E-Cigarettes products (labelling)** 2. **E-Cigarettes products (liquid)** 3. **E-Cigarettes products (devices)**	Product Certification-Type Approval (ECAS Module B)

7. Mandatory Schemes and Applicable Standards:

Cabinet Decision No. 5 of 2019 on a mandatory standard of application in the UAE related to the Emirates System for Implementation of UAE Standards & Mandatory Requirements for E-Cigarettes.

Applicable standards:	
UAE.S 5030:2018	Electronic Nicotine Product (Equivalents of Traditional Tobacco Product)

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 vary depending on the scope of certified products; Details of the documents required for certification for the scope of E-Cigarettes as per Scheme Owner (ESMA) requirements are detailed as following:

8.1. Documents Required:

For E-Cigarettes products (Labelling):

- Application form (Online).
- Valid Industry/Trade License (For Companies within UAE).
- Product card Label and warning label (front and rear face layout of package).
- Distributor ownership (for traders only).
- Declaration of Conformity.

For E-Cigarettes products (Liquid):

- Filled Up Application Form (complete with all information).
- Valid Industry/Trade License (For Companies within UAE).
- ECAS certificate for Electronic device.
- ECAS certificate for product label.
- ECAS certificate for RoHS.
- The product should comply with standard GSO ISO 8317 UAE.S-Resistant packaging for Children.
- Declaration of all additives along with their quantities in descending order by weight also mentioning the trade name, type, reason for adding it and the emissions related.
- Data on doses and nicotine intake when consumed in normal or reasonably expected conditions.
- Study of the validity during the validity period mentioned on the product label
- Test report for the additives and contents of the products.
- Distributor ownership (traders only).
- Declaration of conformity.

For E-Cigarettes products (Device):

- Application Form (complete with all information).

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- Valid UAE Industry/Trade License.
- Trademark/Copyright Registration.
- ECAS Certificate for ROHS
- RoHS Full product Test report from IEC 17025 accredited laboratory – tests in accordance to IEC 62321 standard
  -17025 Accreditation Certificate of the Testing Laboratory
  -Declaration of Compliance
- Safety Test Report as per IEC standard No. UAE S. GSO IEC 60335-1
- Battery Test Report as per IEC standard No. UAE S. GSO IEC 62133
- Electromagnetic compatibility (EMC) test report
- Product Artwork/Packaging Box
- Rating label/plate on the product.
- User Manual in Arabic and English description
- Electronic Declaration of Conformity.

8.2. Legal Agreements:

- Certification Agreement:
- Non-Disclosure Agreement
- General Conditions for Certification Services

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 follows:

9.1.1. Application Form (Refer to table 9-A) shall be submitted by applicant to RACS, submission can be done via RACS convenient communication methods (mail, emails, hard copy, website, E-System).

9.1.2. Sales and Marketing Executive/Administrative Assistant will review it to check documents availability on a primary basis.

9.1.3. A **quotation (RACS/REC/20 Certification Quotation)** will be sent to the applicant by Head of Sales and Marketing Department; containing the scope of certification and fees related to each step of the certification process.

9.1.4. Payment shall be done by the applicant.

9.2. Application Review

9.2.1. Upon acceptance of quotation by client, he is requested to sign the **General Conditions for Certification Services (RACS/Ag/10)**.

9.2.2. Application along with related supportive documents will be received by RACS Conformity Manager who shall assign one of RACS technical team members-Conformity Officer.

9.3. Application Evaluation

9.3.1. Conformity Officer shall perform conformity assessment (Evaluation) steps related to the certification scheme:

Product Certification-Type Approval

- Detailed documents review for all the documents
- Document review includes the checkup 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.

9.3.2. Evaluation Outcome results:

- If the evaluation is pending for missing or invalid documents or other needed information to complete evaluation; additional supportive documents will be requested from the applicant.

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- The 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 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.
- Evaluation will be documented using an Assessment Checklist (Refer to table 9-A for the list Assessment Checklists below for each applicable standard).

9.4 Certification Review

Conformity Manager or his delegates will perform certification review to verify Conformity Officer's recommendation by checking if assessment checklist content is found satisfactory along with complete review for the whole application and supportive documents, and then grant the final recommendation to the Certification Decision Committee. If the review and the certification decision are completed concurrently in the Decision Committee, they shall proceed with the decision after certification review is done.

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 Approval of Product certification: Product evaluation shows full compliance with applicable schemes/standards:
- Certification decision will be done by Decision Committee
- Granting the issuance of Certificate of conformity, recognized by scheme owner (ESMA)
- Certified Products will be listed in RACS **Certified Products Registry (RACS/REC/30).**

9.5.2 Rejection of Product certification: Product evaluation shows non-compliance with applicable schemes/standards, due to any reason preventing product from Certification:
- Rejection decision will be done by Decision Committee
- RACS will inform client/ESMA by an Official rejection statement (Letter of certification Status) by e-mail stating the reason of rejection **(Decision Letter-RACS/REC/71).**

This is being documented by completing the Certification Decision Record;
RACS/REC/99 Certification Decision for Product Certification-Document Review.

Table 9-A Specific Forms

TITLE OF DOCUMENT	IDENTIFICATION
Application Form	TBC/REC/02
Assessment Checklist - UAE.S 5030:2018 E-Cigarettes Product (Labelling)	TBC/REC/13
Assessment Checklist - UAE.S 5030:2018 E-Cigarettes Product (Liquid)	TBC/REC/14
Assessment Checklist - UAE.S 5030:2018 E-Cigarettes Product (Device)	EGA/REC/36

Table 9-B 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
General Conditions for Certification Services	RACS/AG/10
List of Certified Products	RACS/REC/30
Schedule of Fees	RACS/REC/46

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Certification Quotation	RACS/REC/20
Certification Decision-Product Certification	RACS/REC/99
Final Decision Letter	RACS/REC/71

10. Uploading of Certificates in ESMA system:

As a Notified Body, it is the responsibility of RACS to transfer the information to the scheme owner by uploading the Certificate of Conformity and other relevant documents in the scheme owner's (ESMA) online portal. The steps after the Certification Decision (only when recommendation is approved) are as follows;

a) Upon receiving the approval of the Decision Committee, the file should be given back to the responsible Conformity Officer.
b) The CO shall communicate with the Accounts Department to arrange for the payment in ESMA portal.
c) When the payment is posted, the CO shall be able to retrieve the certificate no. and QR code from ESMA portal.
d) The Conformity Officer shall assign a Conformity Assistant to prepare the draft certificate. Along with this, the Conformity Officer shall provide correct and accurate information to the Conformity Assistant.
e) The draft certificate should be sent to the client for their confirmation. Once it is confirmed, final certificate shall be shared to the client.
f) The Conformity Assistant should then upload the certificate in ESMA portal including the product list that should contain the necessary information such as model no., barcode, brand name, product description, country of origin, report no., applicable standard, etc.

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 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).
- 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.

11. Renewal:

Product Certification
Validity of certificate is one year, Certificate of Conformity (CoC) should be renewed 2 months prior expiry.

12. Process Map:

13. 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 the immediate basis on the non-conformity products to take the appropriate action.

14. Sampling Procedure: Please refer to RACS/SOP/21 Sampling Procedures.

15. Acceptance of Conformity Assessment Results: Please refer to RACS/SOP/23 Pre-Certification Procedures

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16. **Outsourcing of the conformity assessment activities:** Please refer to RACS/SOP/06-Sub-contractors Qualifications & Competence Evaluation Criteria

17. **Complaints and Appeals:** Please refer to RACS/SOP/07 Complaints Handling Procedure
18. **Licensing and Control of the Mark:** Please refer to RACS/SOP/01 Procedure of Control the Use of RACS Quality License, Certificate and Mark of Conformity & Scheme Owner's Certificates and Mark of Conformity

19. **Surveillance:** Please refer to RACS/SOP/24 Post Certification Procedures.

20. **Non-conforming products:** Please refer to RACS/SOP/24 Post Certification Procedures

21. **Reporting to the scheme owner-**Please refer to RACS/SOP/39 Dissemination of Significant Information to the Scheme Owner and Other Concerned Parties.

22. **Subcontracting of the operation of the scheme**-Please refer to the relevant scheme.

23. **Marketing**-Please refer to RACS/SOP/72 Marketing Policies and Procedures.

24. **Fraudulent claim of certification-** Please refer to RACS/SOP/01 Procedure of Control the Use of RACS Quality License, Certificate and Mark of Conformity & Scheme Owner's Certificates and Mark of Conformity.

25. **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.
- 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.

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Revision History:

Date	Revision #	Description of Changes
June 18, 2019	00	Initial
August 6, 2020	01	Documents required for For E-Cigarettes products (Device) on page2 are revised.

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