1. Certification Procedures:

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

9.1. Preparatory Steps:

9.1.1. Self- Assessment checklist and 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)

9.1.2. Administrative assistant will review it to check documents availability on a primary basis

9.1.3. A quotation will be sent to applicant by Operations Manager; containing the scope of certification and fees related to each step of the certification process.

9.1.4. Payment shall be done by applicant.

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9.2. Application Review

9.2.1. Upon acceptance of quotation by client, he is requested to Sign the Certification agreement.

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-(Evaluator or Auditor)).

9.3. Application Evaluation

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

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IMPORTANT: as per scheme requirments, Facility Audit is required for this scope:

- On-Site Audit to the facility where the product is being manufactured to assure the quality management system adopted in full compliance with applicable standards and technical regulations.

9.3.2. 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.

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

9.4.1. 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 Managing Director
- Granting the issuance of Certificate of conformity, recognized by ESMA
- Certified Products will be listed in RACS Certified Products registry.

9.4.2. 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 Managing Director
- RACS will inform client by an Official rejection statement (Letter of certification Status) by e-mail stating the reason of rejection.

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 make arrangements for required audits and Certification.
- Client seeking extension or renewal of Certification scope shall as well submit the self- assessment checklist 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 Self-Assessment Checklist requirements and submitted along with the application as well.

2. Renewal:

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

3. 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.