PRODUCT CERTIFICATION SCHEME FOR MECHANICAL-PERSONAL PROTECTIVE EQUIPMENT

1. Objective:

This procedure describes the criteria implemented by RACS as Notified Body of Emirates Authority of Standardization and Metrology (ESMA) that **Mechanical–Personal Protective Equipment** 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 through RACS Quality Certificates Issuing Services as ESMA Notified Body by issuing certificates of conformity in accordance with scheme owner (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 Mechanical-Personal Protective Equipment 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 Mechanical **Personal Protective Equipment** with below details of Sector, scope of certified products, products categories, and applicable type of certification:

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Classification	Type of Certification
Class I Low Risk	ECAS- Model A (Mandatory) EQM - Model H (Voluntary)
Class II Medium Risk	ECAS - Model B (Mandatory) EQM - Model H (Voluntary)
Class III High Risk	EQM - Model H (Mandatory)

Sector (Product Group)	Scope of Certification (Scope of Products)	Product categories	Type of Certification
Mechanical	**Personal Protective Equipment**	• Head Protection • Hand Protection • Eye and Face Protection • Body Protective Clothing • Foot Protection • Hearing Protection • Respiratory Protection • Fall Management Equipment	**Depends on Classification**

Definition by Class

Class I: Simple PPE, PPE in this category is designed to protect users against minimal risks. These include as examples: Ski goggles - Swimming and/or diving goggles, Sports equipment protecting against minor impacts from falling (protection against bruises, abrasion, light burns), such as volleyball knee pads, contact with water or cleaning materials of weak action; contact with hot surfaces not exceeding 50°C; damage to the eyes due to exposure to sunlight (other than during observation of the sun); atmospheric conditions that are not of an extreme

Class II: All equipment protecting hearing (whether worn in or over the ear) includes risks other than those listed in Categories 1 and 3. The following products are included as examples: Safety spectacles and goggles, Industrial helmets and bump caps, hi visibility clothing.

Class III: Complex PPE, includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health' Risks include: substances and mixtures which are hazardous to health; atmospheres with oxygen deficiency; harmful biological agents; ionizing radiation; high-

temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C; low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less; falling from a height; electric shock and live working; drowning; cuts by hand-held chainsaws; high pressure jets; bullet wounds or knife stabs; harmful noise.

Please refer to the link above for the categories of PPE.

7. Mandatory Schemes and Applicable Standards:

The cabinet resolution No. (3) for 2016 UAE conformity assessment Scheme for Personal Protective Equipment (PPE)

Please see attached scheme in Annex 1 for the list of applicable standards.

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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 Mechanical Product as per Scheme Owner (ESMA) requirements are detailed as following:

8.1. Documents Required:

-Application Form (Online/Manual)
-Valid UAE Industry/Trade License
- Test Report from accredited laboratory as per the requirement of applicable standard for the product
- Declaration of Conformity by the Applicant on the Product(s) for Registration using the company's Official Letterhead
- User Manual of the products
- Quality procedure Plan of the products

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 following:

9.1. Preparatory Steps:

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.
- 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

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TITLE OF DOCUMENT	IDENTIFICATION
Application Form	PSE/REC/01
General Assessment Checklist for PPE	PSE/REC/13

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
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 and 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 and 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

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

12. Process Map:

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Product Certification.pdf

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 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

16. Outsourcing of the conformity assessment activities: Please refer to RACS/SOP/06-Sub-contractors Qualifications and 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 and 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 and 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.
- The cabinet resolution No. (3) for 2016 UAE conformity assessment Scheme for Personal Protective Equipment (PPE).

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Revision History:

Date	Revision #	Description of Changes
Sep 1, 2017	00	Initial
June 5, 2018	01	Change from Managing Director to Decision Committee in 9.4. Replaced Operations Manager to Head of Sales and Marketing. Added RACS/Ag/10 General Conditions for Certification Services
August 23, 2018	RACS/PCS/19/Rev00	Changed the reference number from RACS/SOP/50 to RACS/PCS/19. Added references to be inclined with ISO 17067. Changed Process Map; added reference documents. Added the steps for uploading of certificates in ESMA system.
December 15, 2020	01	Update clause 6 with a table of Classification and type of certification and also the definition of Class.