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## PRODUCT CERTIFICATION SCHEME FOR METROLOGY SYSTEM

### 1. Objective:

This procedure describes the criteria implemented by RACS as Notified Body of Emirates Authority of Standardization and Metrology (ESMA) that **Metrology System 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 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 Metrology System 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 **Metrology System** with below details of sector, scope of certified products, products categories, and applicable type of certification:

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**PRODUCT CERTIFICATION SCHEME FOR METROLOGY SYSTEM**

Sector (Product Group)	Scope of Certification (Scope of Products)	Product categories	Type of Certification
N. A.	METROLOGY SYSTEM	1. Measurements Industrial system (IMS)	Product Certification -Type Approval (ECAS/Modul H)- Facility Audit is Mandatory
		2. Conformity of Measuring medical instruments (Blood Pressure Monitors, Thermometers, Glucometers, Syringes)	Product Certification
		3. Conformity of Meters: Taximeters, fuel meters, speed measurements equipment	Product Certification
		4. Non-automatic weighing instruments	Product Certification

**7. Mandatory Schemes and Applicable Standards:**

UAE Scheme No. 9 Of the Year 2017 about the regulations of Metrology Systems  
 Technical regulation for the Legal metrology activities no. 75 of the year 2016.

Applicable Standards:	
OIML R115:2011	Clinical electrical thermometers with maximum device
BS EN 12470-5:2003	Clinical thermometers. Performance of infra-red ear thermometers (with maximum device)
OIML R 16-1:2005	Non-invasive mechanical sphygmomanometers
OIML R 16-2:2005	Non-invasive automated sphygmomanometers
OIML D 26:2009	Glass delivery measures - Automatic pipettes
OIML R 40:2005	Standard graduated pipettes for verification officers
ISO- 3507:2007	Laboratory glassware -- Pycnometers
OIML R 41:2007	Standard burettes for verification officers
ISO 4788:2007	Laboratory glassware -- Graduated measuring cylinders
ISO 7886-1:1993	Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use
UAE.GSO.OIML R76 EEC Directive for NAWI (2009/23/EC)	Non-automatic weighing instruments
OIML R21:2009	Taximeters - Metrological and technical requirements test procedures and test report format
OIML R117:2010	Dynamic measuring systems for liquids \other than water

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.

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## PRODUCT CERTIFICATION SCHEME FOR METROLOGY SYSTEM

### 8. Requirements for Certification:

Requirements varies depending on the scope of certified products; details of the documents required for certification for the scope of Metrology System as per ESMA requirements are detailed as following:

#### Product Certification (ECAS (Module H/Mandatory Facility Visit-IMS Category))

1. Application form (Online).
2. Valid UAE Industry/Trade License.
3. Identifying all legal requirements for each measurement device, its accessories and supportive devices through technical regulations and instructions prepared for that purpose.
4. Test Report of the product issued by an accredited laboratory according to the standards related to each product.
5. Adhering the label marking card for the measurement device.
6. Declaration of conformity by the applicant.

#### 8.1. Legal Agreements:

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

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

### 9. Certification Procedures

#### 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:
- 9.3.2 Evaluation outcome results:

#### Product Certification (Facility Visit Required)

- Detailed documents review for all the documents.
- Document review includes the checkup for Test Reports parameters and results, done by 3<sup>rd</sup> 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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**PRODUCT CERTIFICATION SCHEME FOR METROLOGY SYSTEM**

- 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 3<sup>rd</sup> 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)**.

**Onsite Factory Assessment**

- Upon completion of required interventions, Conformity Officer in charge should contact the Applicant/Trader for any missing/lacking required documents to complete the process.
- The Conformity Officer in charge will also be the one to confirm the dates by completing the **Audit Schedule Form (RACS/REC/13)** of the Factory Assessment Dates/Audits as per the requirement of the standards and availability of the Conformity Officer and Auditee.
- The Conformity Officer in charge will do the **Audit Plan (RACS/REC/45)** as he confirmed the audit dates.
- Factory Assessment will commence once all the required documents have been evaluated, all necessary documents will be forwarded to the Conformity Officers who will be in charge with the Factory Assessment.
- During the Audit, the 1st Conformity Officer will be auditing Factory Compliance as per Quality Management System, while the 2nd Conformity Officer will be auditing as per the technical safety requirements of the standard for the product applied using the **Evaluation Report (RACS/REC/12)**. Additional Assessment Checklists may be required to be filled in by the Conformity Officer depending on the applicable standards of the product being certified. **(Refer to table 9-A for the list Assessment Checklists)**.
- 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.

Once all corrective actions are fulfilled, the Conformity Officer will complete evaluation report **(RACS/REC/12)** summary in evaluation report and shall raise the final evaluation report with his recommendation to the Conformity Manager (or his delegates) for certification review step of the products/facility intended for certification, recommendation is either:

- ✓ Either recommending approval of certification by Issuance of Certificate of Conformity; or
- ✓ Recommending rejection of certification by issuing **Final Decision Letter (RACS/REC/71)**.

**9.4 Certification Review**

Conformity Manager or his delegates will perform certification review to verify the Conformity Officer's recommendation by checking if assessment checklist/evaluation report 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 Recommendation of 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/REC/30-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:

- 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 Document Review or**  
**RACS/REC/100 Certification Decision for Onsite Audit**

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**Table 9-A Specific Forms**

TITLE OF DOCUMENT	IDENTIFICATION
Application Form	IMS/REC/02
Industrial Metrology System Evaluation Report (Assessment checklist).	IMS/REC/04
Assessment Checklist-NAWI	IMS/REC/05
Assessment Checklist-Medical	IMS/REC/06
Assessment Checklist-Taxi meters	IMS/REC/07
Assessment Checklist-Medical Blood Pressure Monitor	IMS/REC/08
Assessment Checklist-Medical Glucometer	IMS/REC/09
Assessment Checklist-Medical Syringes	IMS/REC/10
Assessment Checklist-Speed Measurements (Radars)	IMS/REC/11
Assessment Checklist-Medical Thermometer	IMS/REC/12
Assessment Checklist-Fuel Meter	IMS/REC/13
Application Form-Metrology Product	IMS/REC/14

**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
Audit Schedule Form	RACS/REC/13
Audit Duration Plan	RACS/REC/45
Evaluation Report	RACS/REC/12
Certification Decision-Product Certification	RACS/REC/99
Certification Decision-Onsite Audit	RACS/REC/100
Final Decision Letter	RACS/REC/71

**10. Uploading of Certificates in ESMA system:**

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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-Type Approval

Validity of Certificate is one year and CoC should be renewed two months prior to the expiry.

#### Product Certification with Facility Audit Required:

Validity of certificate is three years, subject to surveillance visits every year during the certification to assure maintenance of conformity. Certificate of Conformity (COC) should be renewed three months prior to the expiry.

### 12. Process Map:

#### Module B-Product Certification



Product  
Certification.pdf

#### Module H-Product Certification with Facility Audit Required



Full Quality  
Assurance.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. Please refer to RACS/SOP/71 Market Monitoring Procedures.

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**PRODUCT CERTIFICATION SCHEME FOR METROLOGY SYSTEM**

- 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 & 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.
  - UAE Scheme No. 9 Of the Year 2017 about the regulations of Metrology Systems.
  - Technical regulation for the Legal metrology activities No. 75 of the year 2016.

**Revision History:**

Date	Revision #	Description of Changes
Nov 1, 2017	00	Initial

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**PRODUCT CERTIFICATION SCHEME FOR METROLOGY SYSTEM**

Jan 28, 2018	01	Added categories for Metrology Scheme. Added new documents in specific records.
June 5, 2018	02	Change from Managing Director to Decision Committee in 9.4. Replaced Operations Manager to Head of Sales and Marketing. Replace Administrative Assistant to Sales and Marketing Executive/Administrative Assistant. Added RACS/Ag/10 General Conditions for Certification Service
August 28, 2018	RACS/PCS/20/Rev00	Changed the reference number from RACS/SOP/60 to RACS/PCS/20. Added references to be inclined with ISO 17067. Changed Process Map; added reference documents.

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