

Product Certification Scheme for Baby Care Products

1. Objective:

This procedure describes the criteria implemented by RACS as Notified Body of Emirates Authority of Standardization and Metrology (ESMA) that CHEMICAL –**Baby Care 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 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 & 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 CHEMICAL –Baby Care 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 –Baby Care 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	Baby Care Products	<ol style="list-style-type: none"> 1. Flexible nipples for baby feeding bottle. 2. Soothers for babies and toddlers. 3. Baby use and care materials - drinking tools. 4. Child use and care articles — Cutlery and feeding utensils. 5. Ready-to-use disposable diapers 	1. Product Certification - Type Approval (ECAS Module B-ESMA)

7. Mandatory Schemes and Applicable Standards:

Emirati system for the control of Baby Care Products, No. 34 Of the Year 2019.

Approved standard for child seat restraints systems

Number	Standard Number	Name of standard
1	UAE.S GSO 2079	Flexible nipples for baby feeding bottle
2	UAE.S GSO 2015	Soothers for babies and toddlers: part 1 General Safety requirement
3	UAE.S GSO 2016	Soothers for babies and toddlers: part 2 Chemical and Tests requirements
4	UAE.S GSO 2073	Soothers for babies and toddlers: part 3 Physical requirements
5	UAE.S GSO 2074	Soothers for babies and toddlers: part 4 testing methods of Physical requirements
6	UAE.S GSO 2164	Baby use and care materials - drinking tools: Part 1 General and Physical requirements
7	UAE.S GSO 2168	Baby use and care materials - drinking tools: Part 2 test methods of General and Physical requirements
8	UAE.S GSO 2163	Baby use and care materials - drinking tools: Part 3 Chemical Requirements
9	UAE.S GSO 2167	Baby use and care materials - drinking tools: Part 4 test methods of Chemical Requirements
10	UAE.S GSO 1833	Ready-to-use disposable diapers
11	UAE.S GSO 839	Food Packaging Materials : Part 1 General requirements
12	UAE.S GSO 1863	Food Packaging Materials : Part 2 Plastic Packages General requirements
13	UAE.S GSO 2231	General requirements of Food Contact Materials

International reference approved standard for Baby Care Products systems

1	EN 14372	Child use and care articles — Cutlery and feeding utensils
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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 Chemical Product as per Scheme Owner (ESMA) requirements are detailed as following:

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8.1. Documents Required:

- Valid UAE Industry/Trade License.
- Test Report from an accredited and recognized laboratory as per One of the below approved Reference:
 - UAE.S GSO 2016: Soothers for babies and toddlers: part 2 Chemical and Tests requirements.
 - UAE.S GSO 2074: Soothers for babies and toddlers: part 4 testing methods of Physical requirements.
 - UAE.S GSO 2168: Baby use and care materials - drinking tools: Part 2 test methods of General and Physical requirements.
 - UAE.S GSO 2167: Baby use and care materials - drinking tools: Part 4 test methods of Chemical Requirements.
 - **Flexible nipples for baby feeding bottle** :GSO 2080 'Test methods for Babies' elastomeric feeding bottle teats', and ISO 8234 'Safety of toys – Migration of certain elements':.
 - **Single – use – Disposable baby diapers** :GSO 750 "Methods of Testing Sanitary Pads for Ladies and Diapers for Babies ", 2.2 GSO 682 "Paper and Board – Sampling to Determine Average Quality ", 2.3 GSO 143 "Methods of Testing Facial Tissue Paper".
 - **Food Packaging Materials** : Part 1 General requirements: GSO 9/1995 "Labelling of Prepackaged Foods", GSO 124/1990 "General Requirements for Fresh Fruits and Vegetables Boxes", Draft GSO Standard on "Hermetically Sealed Round Tin Cans Used for Canning Foodstuffs".
 Food Packaging Materials : Part 2 Plastic Packages General requirements :UAE.S GSO 1863 :2013 Food packages - Part 2: Plastic package - General -requirements Fulfill with the Label requirements mentioned on the product in Arabic language and accompanying instruction manuals.
 - **Food Contact Materials**: UAE.S GSO 2231, GSO-142-2010-E Tableware-Melamine Plastics, GSO-839-1997-E Food Packages
 GSO-ISO-177-2007-E Plastics – Determination of migration of plasticizers
 ISO 6486-2 Ceramic ware, glass ceramic ware
 ISO 7086-2 Glass Hollowware in contact with Food
 ISO 8931-2 Ceramic Cookware
 UAE.S GSO 124 _1990-Gen Req for Fresh Fruits and Veg Boxes
 UAE.S GSO 458 _1994-E Wrapping Paper
 UAE.S GSO 462 _1994-Single use rigid and semi plastic cups
 UAE.S GSO 1024 _2000-E Non-Returnable Glass
 UAE.S GSO 1102 _2002-Milk Paper board containers
 UAE.S GSO 1193 _2002-PET Bags for Food Packaging Applications
 UAE.S GSO 1863 _2013-E Food Packages
 UAE.S_ GSO 1791 _2007-Three piece steel Round Cans
 UAE.S_ GSO 1793 _2007-E Two Pieces Aluminum Round
 UAE.S_ GSO 1794 _2007-Canning Food Stuff
 UAE.S_GSO 2014 _2010-Domestic Cookware
 UAE.S_GSO 2075 _2010-E Cookware made from thermal Glass
 UAE.S_GSO 2138 _2011-E Tea and Herbs bags
 - Child use and care articles — Cutlery and feeding utensils, EN 14372:
- 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 following:

9.1. Preparatory Steps:

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- 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**).

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

Table 9-A Specific Forms

TITLE OF DOCUMENT	IDENTIFICATION
Application Form	BCP/REC/01
UAE.S GSO 2164:2011 – Child use and care articles - Drinking equipment - Part 1: General and Physical Requirements	BCP/REC/02
UAE.S GSO 2079:2010 – Babies Elastomeric Feeding Bottle Teats	BCP/REC/03
EN 14372 – Cutlery and Feeding Utensils	BCP/REC/04
UAE.S GSO 1833:2007 – Single Use Disposable Baby Diapers	BCP/REC/05
UAE.S GSO 2015:2010 - Soothers for babies and young children - Part 1: General safety requirements UAE.S GSO 2016:2010 - Soothers for babies and young children - Part 2: Chemical requirements and tests UAE.S GSO 2073:2010 - Soothers for babies and young children -Part 3: Physical requirements	BCP/REC/06

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.

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- 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 two (2) months prior expiry.

12. Process Map:



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 & 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.

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- 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.
- Emirati system for the control of Child Car Seats, No. 27 Of the Year 2017.

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Revision History:

Date	Revision #	Description of Changes
April 15, 2020	00	Initial

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