

QP-05 – Product system Certification Process

APPROVALS

S. No	Function	Documentation Administration
01	Management Representative	Document Author & Controller
02	Certification Manager	Document Reviewer & Approver

Revision History					
Issue No	Revision No	Revision Date	Revised by	Approval Date	Description of Issue / Revision
01	00				Initial Release (First Issue)

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1. Purpose

To define the systematic process followed by the Certification Body (EPAC) for the **evaluation and certification of products** under the **Saudi Food and Drug Authority (SFDA)** Certificate of Conformity (CoC) scheme, in compliance with **ISO/IEC 17065:2012, ISO/IEC 17067:2013, and SAAC accreditation criteria.**

2. Scope

This procedure applies to all **product categories regulated by SFDA** for import or local market release — including cosmetics, disinfectants, medical devices, and food contact materials — where SFDA requires a Certificate of Conformity to verify product compliance prior to customs clearance.

3. Normative References

- **ISO/IEC 17065:2012** – Conformity Assessment – Requirements for bodies certifying products
- **ISO/IEC 17067:2013** – Fundamentals of product certification and guidelines for product certification schemes
- **ISO/IEC 17025:2017** – Testing and calibration laboratories competence
- **SAAC Accreditation Criteria for Product Certification Bodies**
- **SFDA Technical Regulations & Guidance Documents**
- **GSO / SASO Standards applicable to product type**
- **SFDA Cosmetics Registration Procedures**

4. Definitions

Term	Definition
CoC	Certificate of Conformity issued for a shipment confirming compliance with SFDA technical requirements.
EPAC	Certification Body (e.g., EPAC) accredited by SAAC for SFDA scope.
Applicant	Manufacturer, exporter, importer, or authorized representative submitting the certification application.
Evaluator / Technical Reviewer	Qualified personnel performing document and technical review.
Decision Maker	Authorized person independent from evaluators who makes final certification decision.
SFDA CN Number	Cosmetic Notification number issued by SFDA portal (mandatory for cosmetics).
Scheme Type	Product Certification System Type 5 under ISO/IEC 17067 – includes evaluation, testing, and surveillance.

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5. Responsibilities

Role	Responsibility
Certification Manager	Overall supervision of certification process, review of reports, and final decision authorization. Ensures implementation and compliance with ISO 17065 and SAAC requirements; handles internal audits.
Technical Reviewer	Performs technical evaluation of submitted documentation, test reports, and product data.
Business Developer	Handles client communication, document control, recordkeeping, and CoC issuance.
Impartiality Committee	Reviews impartiality risks annually as per Clause 4.2 of ISO 17065.

6. Certification Process Flow

6.1 Application Receipt and Review

Reference: ISO 17065 – Clause 7.2

1. Applicant submits **Certification Application Form** with:
 - Invoice & Packing List
 - Product Name, Brand, and Model details
 - Manufacturer details and address
 - SFDA Registration (CN/CRN) Numbers
 - Product Label Artwork (English/Arabic)
 - Test Reports from ISO 17025 Accredited Laboratory
 - Safety Data Sheet (if applicable)
 - GMP Certificate / Manufacturing License
 - Declaration of Conformity
 - Importer/Distributor details in KSA
2. **Application completeness check** performed by Certification Officer.
 - If incomplete → request missing documents.
 - If product not under SFDA scope → reject and inform applicant.

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6.2 Application Review and Contract Formation

Reference: ISO 17065 – Clause 7.2.2, 4.1

1. Certification Manager reviews application for:
 - Product category eligibility
 - SFDA regulation mapping
 - Applicable standards (GSO, ISO, SFDA TR)
 - Test report validity (≤ 1 year, accredited lab, standard compliance)
 - CN Number validation (from SFDA portal screenshot)
2. Issue **Quotation & Service Agreement** stating scope, fees, rights, and obligations.
3. Upon acceptance, assign a **Unique Application Number**

6.3 Planning & Execution of Inspection

a) Verification of Documentation:

- Compare product name, batch, and CN Number on the packaging with approved documents.
- Ensure labels, expiry dates, and ingredients match the test report.

b) Visual Examination:

- Packaging integrity, labeling clarity (Arabic + English), net quantity.
- Absence of damage, leakage, or contamination.

c) Sampling (if applicable):

- Randomly select representative samples per ISO 2859-1 or GSO ISO 2859 sampling plans.
- Seal and label samples; issue **Sample Handover Form**.
- Dispatch samples to an **ISO/IEC 17025-accredited laboratory** for verification testing.

d) Photography & Evidence:

- Capture photographic evidence of product, packaging, and labeling.
- Store photos as part of the inspection file

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6.4. Final Evaluation & decision

a) Document Review

- Cross-check of product name, batch, and invoice with test reports.
- Ensure sample tested corresponds to shipment product.

b) Label Review

- Verify bilingual labeling (English & Arabic).
- Check mandatory labeling content:
 - Product Name
 - Manufacturer name & country
 - Batch / Lot Number
 - Net content
 - Expiry date (if applicable)
 - Precautionary statement (“For external use only”, etc.)

c) Standards and Regulation Review

- Mapping against specific SFDA technical regulation:
 - e.g., *SFDA.TR.CO/2021/01 – Cosmetic Product Safety*

d) Verification of SFDA Registration

- CN number validity confirmed from SFDA system or client submission.
- If expired or under review → hold the process.

Technical Reviewer prepares a **Technical Evaluation Report** summarizing compliance status and deviations.

6.5 Nonconformity and Corrective Action

Reference: ISO 17065 – Clause 7.4.3

- Any nonconformities identified are communicated to applicant via **Corrective Action Request (CAR Form)**.
- Applicant must submit evidence of correction within defined timeframe (typically 10 working days).
- Reviewer verifies and closes NCs before proceeding.

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6.6 Certification Decision

Reference: ISO 17065 – Clause 7.6

- Decision made by **Certification Decision Committee** independent of evaluators.
- Decision options:
 - **Approved** – proceed with CoC issuance
 - **Deferred** – pending additional info
 - **Rejected** – due to noncompliance (communicated in writing)

6.6 Certificate of Conformity Issuance

Reference: ISO 17065 – Clause 7.7

Once approved, EPAC issues a **shipment-based CoC** in English & Arabic, including:

- Certificate Number: *EPAC-CER-00X*
- Date of Issue
- Product Description (Name, Brand, CN)
- Quantity and Unit
- Manufacturer Name & Address
- Importer Name & Address (KSA)
- Test Report References
- Standard References (GSO ISO / SFDA TR)
- Certification Statement:
“This certificate confirms that the listed products have been verified and found in compliance with the applicable SFDA technical regulations and standards.”
- Signature & Stamp
- QR Code (if applicable for traceability)

All CoCs are digitally archived under controlled document register.

6.7 Record Keeping

Reference: ISO 17065 – Clause 8.4

- Application file retained for a **minimum of 5 years** after certificate expiry.
- Electronic files stored in secure drive with access control.

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- Records include:
 - Application Form
 - Test Reports
 - Technical Evaluation Report
 - CoC copy
 - Communication records
 - Decision form

Reference: ISO 17065 – Clause 7.9

- Random post-shipment checks or sample testing may be performed by EPAC or SFDA.
- Re-certification required for new shipments or modified products.
- Major changes (composition, label, CN expiry) trigger **re-evaluation**.

6.9 Complaints and Appeals Handling

Reference: ISO 17065 – Clauses 7.13 & 7.14

- Complaints logged in **Complaint Register**
- Investigated by impartial personnel.
- Appeal process available within 15 days of decision notification.
- Outcomes communicated formally to appellant.

7. Impartiality and Confidentiality

- All staff must sign the **Impartiality Declaration**
- Certification decisions are based solely on objective evidence.
- Client and product data treated as confidential as per ISO 17065 Clause 4.5.

8. Document Control

- This SOP is controlled under **EPAC Quality Manual**, section “Product Certification Procedures.”
- Revisions approved by Quality Manager.
- Obsolete versions retained and stamped “Superseded.”

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9. Appendices

Appendix A – Process Flowchart

(Application → Review → Evaluation → Decision → Issuance → Record)

Appendix B – Example CoC Format (Bilingual)

Appendix C – Technical Review Template

Appendix D – Reference Standards List

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Annexure A – Certification Process Flowchart

Colour-coded flowchart for SFDA CoC Certification Process (as per SAAC / ISO 17065).

