Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Food & Drug Authority

Guidance on the Requirements of Designation of Conformity Assessment Bodies (CAB)

Version No. 3 - 1442 AH

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Introduction:

1. Introduction:

The Saudi Food & Drug Authority prepared this Guidance based on Article (22) of Saudi Food and Drug Authority Law promulgated by Royal Decree No. (M/6) dated 25/01/1428 AH, which stipulates: "SFDA may employ government or private bodies to perform some of its missions", and Article (22) of the law executive regulation issued by the SFDA Board Resolution No. (7-7-1428) dated 25/07/1429 AH, which stipulates: "SFDA shall set licensing controls and requirements for private laboratories and conformity verification offices whose specialization falls within the scope of work of SFDA, in addition to the requirements and procedures for accreditation of certificates issued by such laboratories and offices".
Based on the "Designation Regulation of Conformity Assessment Bodies (CAB)" issued by Board Resolution No. (5-20-1440) dated 07/09/1440 AH, amended by the SFDA Board Resolution No. (1-33-1443) dated 16/09/1443 AH.

Purpose:

The purpose of this Guidance is to set the technical requirements for conformity assessment bodies to obtain designation certificate from SFDA for performing missions related to SFDA according to the designation scope.

Scope of Application:

This Guidance applies to the conformity assessment bodies in the Kingdom of Saudi Arabia or abroad, which apply for obtaining designation certificate from SFDA to perform any of the missions assigned thereto.

Definitions

The following terms and expressions, whenever mentioned in this Guidance, shall must have the meanings assigned thereto, unless the context requires otherwise, in addition to the terms and definitions set forth in the bylaws issued by SFDA.

SFDA

Saudi Food & Drug Authority.

Establishment

Any legal entity in which one or all of the trade stages of the products subject to the control of SFDA is conducted

Conformity Assessment Body

The body that verifies the conformity of the products and/or establishments to the conditions and requirements of SFDA, including inspection bodies, certification bodies, laboratories, and any other conformity assessment bodies that SFDA adds to its activity in the future, including private laboratory.

Testing Conformity Assessment Body:

The body that conducts tests and measurements related to the SFDA's scope of work under standard circumstances, whether the private laboratory is independent or belongs to the conformity assessment body.

Designated Body

The accepted body authorized and designated by the designation authority (Saudi Food & Drug Authority) to perform the conformity assessment procedures or the tests specified in the technical regulations and standards of the products under its supervision according to the body's designation scope.

Designation

Government authorization for a conformity assessment body or a private laboratory to perform specific activities to assess the conformity of a product, process, system, person, or entity that has been met

Scope of Designation

A specific scope of work provided by the conformity assessment body or a private laboratory on behalf of SFDA.

Conformity Assessment

Verifying that the conditions and requirements set by SFDA in relation to a product, process, system, person or entity are fulfilled.

Accreditation

A certificate from a third party for a conformity assessment body, officially confirming that such laboratory or body is efficient, objective and follows consistent processes for performing specific conformity assessment activities

Test

Each analysis, standardization or examination that aims at identifying the characteristics of performance, efficiency, effectiveness or conformity.

Inspection

Examining products, competencies, entities, establishments, processes, services, systems, work methods, projects, data, designs, materials or allegations, and determining their conformity to specific requirements or according to a professional rule based on general requirements.

Certification

A mechanism whereby one of the conformity assessment bodies implements (examination and testing / inspection) processes, verifies and confirms that a (product/ service/ process/ system) implements the conformity assessment procedures set forth in the relevant regulation or technical standard.

Product

Everything that results and is released from any manufacturing or analytical process or set of processes for the purpose of consumption or use.

Sampling

An activity related to obtaining a sample that represents the conformity assessment item in accordance with the procedure.

Conformity Certificate

A third party authentication with regard to products, processes, systems or persons.

Product Conformity Certificate

A conformity certificate for the products that are subject to the technical regulation, so that samples are periodically analyzed to make sure that the product conform to the technical regulations and standards that the product must meet, which are approved by SFDA, and the product has been withdrawn from the certification body.

Consignment Certificate of Conformity

A certificate confirms that the product imported in the consignment, with invoice number and batch number stated in the certificate, conforms to the conditions and requirements of SFDA, and the product has been withdrawn from the certification body.

Accreditation Body

The Saudi Accreditation Center for local bodies or an accreditation body that is a member of International Accreditation Forum (ILAC-IAF) for foreign bodies.

02

Conditions and Requirements of Designation License of Conformity Assessment Bodies

Second

2. Conditions and Requirements of Designation License of Conformity Assessment Bodies

2.1 General Conditions:

1. The existence of a legal entity for conformity assessment bodies and testing conformity assessment bodies in the Kingdom of Saudi Arabia to approve the application of designation.
2. The testing conformity assessment bodies must obtain the certificate of designation from SFDA to perform the missions related to the designation areas.
3. The owner must be a Saudi national or a foreign investor licensed by the Ministry of Investment.
4. Having the activity practice license for conformity verification bodies, quality management system and quality assurance system for medical devices and supplies.
5. The conformity assessment body must be accredited for the required area of designation by the Saudi Accreditation Center (SAAC) for local bodies or any accreditation body that is a member of the International Accreditation Forum (ILAC-IAF) for foreign bodies, as deemed appropriate by SFDA.
6. Commitment to the fees mentioned in the regulation when adding a new area or tests in the certificate of designation for the conformity assessment bodies.
7. When submitting the application to SFDA, the applying conformity assessment body must identify the area in which it wants to work, through identifying the relevant regulations, the conformity assessment procedures and forms, and the certificates of conformity, which it has the technical ability to undertake (SFDA Scheme).
8. The conformity assessment body must inform SFDA immediately if it cannot fulfill the conditions and requirements of the designation anymore.
9. The conformity assessment body must conduct the technical assessment processes and certification through the body's branch in the Kingdom of Saudi Arabia, whether the owner is a Saudi national or a licensed foreign investor.

10. The body's branch in the Kingdom of Saudi Arabia must keep all documents related to the issued certificates and submit them to SFDA upon request.
11. The conformity assessment body must inform all customers once the laws or the technical regulations, related to their work, that are part of the certificate requirements are changed or updated.
12. The conformity assessment body must update the assessment and testing procedures contained in the technical regulations issued by SFDA, including but not limited to the following:

- Assessment and testing procedures set forth in the technical regulations approved by SFDA.
- Standards and procedures for assessment of production processes and audit of quality management systems.
- Standards and procedures of inspection.
- Standards of technical competence required for conformity assessment body.
- Procedures of the conformity assessment bodies participating in the SFDA program.

13. The conformity assessment body must ensure that the customer informs it of any modification to the product and/or production process and/or quality management system. If any modifications are made, the conformity assessment body must verify whether they affect the product conformity or not, and decide whether the customer is allowed to market such products under the previous certificate, so that the conformity assessment body can verify the necessity to retest and reassess.
14. If the customer is desirous to expand the scope of license to include additional products that fulfill the requirements set for products previously certified according to the technical annex to the certificate, the conformity assessment body may decide not to assess the product and/or production process and/or quality management system, provided that the justifications for the same are documented. The procedures followed to decide on the conformity of such additional products must be documented. When the scope of certificate is expanded by adding other products, the agreement between the customer and the conformity assessment body must be amended to include such products.

15. When the certificates of quality management systems (ISO/IEC 13485, GMP, ISO/IEC 22000 and HACCP) or equivalent certificates, and the test results are provided by the customer to the conformity assessment body, as part of fulfilling the SFDA's requirements, the conformity assessment body must verify the following:

- The conformity assessment results provided by the customer are issued from conformity assessment bodies accredited by ILAC-IAF for the following standards: (ISO / IEC 17025 / IEC 17020 or ISO / IEC 17021).
- The test results provided by the customer meet the requirements mentioned in the technical annexes, provided that the samples are taken by the conformity body.

2.2 Outsourcing foreign bodies for the performance of the missions assigned to the conformity assessment body

In case of contracting with foreign bodies or individuals for performing some of the conformity assessment body's missions, the following conditions must be met:

1. Obtaining the approval of SFDA before completing the contracting process, and comply with the general requirements. Inserting all contracts with foreign bodies or individuals to carry out some of the conformity assessment body's missions in GHAD system when requesting designation, and adhering to the requirements, knowing that this approval does not relief the conformity assessment body from responsibilities and obligations.
2. Contracting with a legal entity that have the required accreditation, according to the activity to be conducted by the foreign body.
3. Contracting with a person who fulfills the technical competence requirements, according to the activity to be conducted by the foreign body.
4. Providing SFDA via GHAD system with technical and legal contracts with regard to the designation areas, and notifying SFDA of any contract or change to contract.
5. The conformity assessment bodies that issue certificates and desires to outsource foreign bodes must ensure that such bodies fulfill the requirements as set forth in the SFDA Scheme approved for the conformity assessment body.
6. The conformity assessment bodies must verify that the foreign bodies that conduct tests adopt the requirements applicable in ISO / IEC 17025.
7. The conformity assessment bodies must verify that the foreign bodies that conduct inspections adopt the requirements applicable in ISO / IEC 17020.
8. The conformity assessment bodies must verify that the foreign bodies that conduct quality management system audits adopt the requirements applicable in ISO / IEC 17021.
9. The conformity assessment body must verify that persons fulfill the required accreditations and competences as specified in the technical annexes according to the designation area.

10. The conformity assessment body must verify that the foreign bodies or individuals fulfill the neutrality requirements set forth in Standard (ISO/IEC 17025, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17065), including provisions of confidentiality and conflict of interests.

11. The conformity assessment body that issues certificates must have a legally binding contract with the bodies that provide external service (inspection and testing) as specified in Standard ISO/IEC 17065.

12. All conformity assessment bodies must provide a list of all branches of the body outside the Kingdom of Saudi Arabia or the bodies contracted as foreign bodies undertaking the missions of the conformity assessment body, in addition to providing the legal contracts concluded with such bodies, provided that SFDA be provided with any update to the list.

13. The conformity assessment bodies must analyze samples in the laboratories accrediting the type of tests, in accordance with the scope of accreditation ISO/IEC 17025.

14. When nondependent foreign body is outsourced, the conformity assessment body must take the following into consideration:

- Customers' laboratories and conformity assessment bodies' laboratories: The conformity assessment body that issues the certificates must make sure that the laboratory obtains ISO/IEC 17025 accreditation before accepting the results issued from the laboratory, provided that samples are taken by the conformity assessment body.
- Branches of conformity assessment bodies that are not legally connected directly with the branch of the conformity assessment body in the Kingdom of Saudi Arabia must comply with the requirements specified in Clause 2.11.

2.3 Conformity Assessment Bodies' Designation License Areas

1. Inspection						
Product	**Designation Area**	**Verification Procedures**	**Mandatory Application**	**Adoption of Required Area**	**Fees (SAR)**	
					Designation and Renewal	Country Addition
Food	Inspection to accept export establishments to the Kingdom of Saudi Arabia	Technical Annex - Inspection Report (Food)	Countries determined by SFDA and as per the risk assessment	ISO/IEC 17020	20,000	1,000
Cosmetic	Establishment inspection	At the request of SFDA and as per the Technical Annex – inspection report (cosmetic)	As per the risk assessment	ISO/IEC 17020	20,000	1,000
Medical Devices and Supplies	Inspection of medical devices and supplies establishments subject to the Law	Verifying that medical devices and supplies establishments comply with the SFDA's requirements	As per the risk assessment	ISO/IEC 17020	20,000	1,000

2.3 Conformity Assessment Bodies' Designation License Areas

2. Certification						
Product	**Designation Area**	**Verification Procedures**	**Mandatory Application**	**Adoption of Required Area**	**Fees (SAR)**	
					Designation and Renewal	Country Addition
Food	Consignment conformity certificates	Technical Annex to the Guidance on the Requirements of Designation of Conformity Assessment Bodies	As published on the SFDA's website	Technic al annex	20,000	1,000
Cosmetic	Product conformity certificates	Technical Annex to the Guidance on the Requirements of Designation of Conformity Assessment Bodies	As per the risk assessment and the products specified by SFDA	Technic al annex	20,000	1,000
	Quality system management certificates for establishments	Technical Annex to the Guidance on the Requirements of Designation of Conformity Assessment Bodies	As specified by SFDA	ISO/IEC 17021	40,000	

2.3 Conformity Assessment Bodies' Designation License Areas

	Consignment conformity certificates	Technical Annex to the Guidance on the Requirements of Designation of Conformity Assessment Bodies	As per the risk assessment and the products specified by SFDA	Technic al annex	20,000	1,000
	Product conformity certificates	Technical Annex to the Guidance on the Requirements of Designation of Conformity Assessment Bodies	As per the risk assessment and the products specified by SFDA	Technic al annex	20,000	1,000
	Quality system management certificates for establishments	Technical Annex to the Guidance on the Requirements of Designation of Conformity Assessment Bodies	As specified by SFDA	ISO/IEC 17021	40,000	
Medical Devices and Supplies	Quality system management certificates for establishments	Verifying the conformity of the quality management system certificates for medical devices (ISO/IEC 13485)	As per the Medical Devices Law and as specified by SFDA	ISO/IEC 17021	40,000	

* SFDA must collect a fee for each consignment conformity certificate (SAR 1,000/certificate).
* SFDA must collect a fee for each product conformity certificate (SAR 1,000/certificate).
* The validity of the conformity assessment body's designation certificate is (3) three years.

2.4 Requirements for Licensing the Designation of Conformity Assessment Bodies as per each Area

2.4.1 Inspection Activity Requirements

1. The conformity assessment body must be an accredited body in accordance with the requirements of the international standard (ISO/IEC 17020) for the branch in the Kingdom of Saudi Arabia by the Saudi Accreditation Center (SAAC) as a prerequisite for accreditation of the area in the event that inspections are conducted in the Kingdom of Saudi Arabia.
2. Complying with all technical regulations, specifications and circulars to ensure their application depending on the type of establishment, factory and product as specified by SFDA.
3. The ability and competence of the specialists to inspect the entire establishment and its employees.
4. Complying with all of the technical details mentioned in the technical annex on the inspection reports for establishments and factories, and not issuing any reports that do not comply with the same.
5. Issuing the report on the acceptance of the establishment.

2.4.2 Certification Activity Requirements

2.4.2.1 Consignment Conformity Certificates and Product Conformity Certificates

1. The conformity assessment body must be an accredited body, in the area in which designation is desired in accordance with the requirements of the international standard (ISO/IEC 17065) for the branch in the Kingdom of Saudi Arabia, by the Saudi Accreditation Center (SAAC) as a prerequisite for accreditation of the area.

2. All technical assessments must take place in the branch in the Kingdom of Saudi Arabia.
3. The conformity assessment certificate must be awarded only after verifying the relevant international conditions, requirements, circulars and standards in accordance with the forms approved by SFDA.
4. Keeping reports of non-conformities detected during the technical assessments and corrective measures taken, and providing SFDA with them if requested.
5. Providing SFDA with statistics and regular reports, upon request.
6. Informing SFDA of any changes to the data of the conformity assessment body or the establishment that obtained any certificate from it, or other changes in the data kept with SFDA.
7. Cessation of certification in the event that its activity is suspended by SFDA or by the accreditation body.
8. Retaining all papers and documents related to the certificate after the expiry of the designation certificate for (5) five years.
9. Commitment to the methods of physical and laboratory examination in accordance with the laws, executive regulations, standards and requirements approved by SFDA in internationally accredited laboratories in accordance with the international standard (ISO/IEC 17025). If unavailable, SFDA must be referred to in order to determine the examination methods, taking into account the updates made to the technical regulations, specifications and any new specifications and standards.
10. The possibility of clearing the consignment that has a valid product conformity certificate for the same products in the consignment without issuing a consignment conformity certificate, with only one of the conformity certificates in a manner that does not contradict any regulations adopted by SFDA in the future.
11. Complying with all of the technical details mentioned in the technical annex on the consignment conformity certificate and product conformity certificate, and not issuing any conformity certificates that do not comply with the same.
12. Not issuing conformity certificates that are not included as part of the products mentioned in the technical annex on the consignment conformity certificates and product conformity certificate.

2.4.2.2 Requirements for the Area of Quality Management System for Establishments: (General)

1. The conformity assessment body must be an accredited body, in the area in which designation is desired in accordance with the requirements of the international standard (ISO/IEC 17021) for the branch in the Kingdom of Saudi Arabia, by the Saudi Accreditation Center (SAAC) as a prerequisite for accreditation of the area.
2. Surveillance visits must be carried out by the conformity assessment body in accordance with (ISO/IEC 17021).
3. The validity of quality management system certificates for establishments is (3) three years.
4. Complying with all of the technical details mentioned in the technical annex on the quality management system certificate and inspection reports for establishments and factories, and not issuing any certificates or reports that do not comply with the same.

2.4.3 Additional Requirements for Designation License of Testing Conformity Assessment Bodies

1. The testing conformity assessment body must have a valid license from SFDA for the same area in which it desires to designate.
2. The testing conformity assessment body must be accredited according to ISO/IEC 17025 in the same tests that were applied for the Saudi Accreditation Center (SAAC) for designation with SFDA.
3. Testing methods for each item must be provided, according to the product type in the special requirements.
4. Developing a mechanism for deciding whether the test results are accepted by the testing conformity assessment body or not, provided that such mechanism includes all assessment courses, so that the testing conformity assessment body can verify that the conformity assessment results are related to the accreditation requirements, such that the results can be accepted or rejected in accordance with the standards or regulations approved by SFDA.
5. Complying with the conditions and requirements of the updated Private Laboratories Law promulgated by Royal Decree No. (M/31) dated 06/04/1443 AH and its executive regulation.

6. Participation in the Proficiency Tests required by SFDA, according to the requirements of (ISO/IEC 17043).
7. Complying with providing all tests specified for the area of designation, according to the product and item type and price in the list of designation accredited by SFDA, and complying with the approved laboratory methods and the scope of analysis listed on the SFDA's website, if any.
8. Complying with issuing test results in accordance with laws, technical regulations, conditions and requirements related to the same, while assuming the legal liability for any damage arising of the same no later than (15) fifteen working days from the sample receipt date.
9. Providing a mechanism for transporting samples from ports and sending them to the laboratory through appropriate means of transportation and conditions.
10. When applying for designation, the laboratory must provide the minimum tests referred to in the designation list approved by SFDA, so that they can be conducted in the laboratory. (additional Annex - Clause 3).
11. If there is a desire to add new area in the designation certificate, the area must be licensed and added to the laboratory license.
12. The designated laboratory must follow all bylaws, regulations, guidelines, conditions, requirements, circulars and instructions issued by SFDA in relation to the area of designation once issued, and any amendments or additions to the same on the SFDA's website.
13. Responding to SFDA in sending the regular reports or anything required by SFDA.
14. The laboratory must close the points of non-conformity detected during the SFDA's technical assessment visit and provide a corrective plan no later than (2) two weeks from receiving the visit report.

2.5 Workflow Mechanism for Submitting Designation/Renewal/or Addition License Application:

Creating an account in GHAD System	Submitting the application Reviewing the application,	Reviewing the application, after fulfilling the SFDA's requirements	Paying the fees	Issuing a designation license	Inspection visit

2.6 Requirements for Licensing the Designation of Conformity Assessment Bodies:

Required Documents	Details
Approval of the competent authority to site licensing	The license must be valid and issued from an accredited authority in the Kingdom of Saudi Arabia.
Commercial Register	The commercial register must be valid and include an activity related to the designation area.
Accreditation certificate and accreditation annex issued by the competent authority	A detailed statement of the accreditations obtained by the body for the branch in the Kingdom of Saudi Arabia from the Saudi Accreditation Center (SAAC) or any accreditation body that is a member of the International Accreditation Forum (ILAC-IAF) covering the designation area and not added as a branch (key location) in the certificate.
Bank Guarantee	Providing a bank guarantee of SAR (200,000) for the Saudi Food and Drug Authority throughout the validity of the designation license.
Organizational structure and list of technical and administrative staff data	Include the following: The staff of the conformity assessment body must have sufficient relevant knowledge and experience to perform the assessment activities and issue conformity certificates in accordance with the requirements of the relevant regulations and standards. A letter of undertaking the validity of the data and informing SFDA in the event of a change in the technical or administrative staff.
Liability insurance policy for the conformity assessment body	A valid insurance policy that covers professional errors during the practice of conformity assessment works issued from an entity approved by the Central Bank of Saudi Arabia.

- Payment of the designation fees.
- After fulfilling the requirements, the designation license is issued through GHAD System in the required designation area for a validity period of (3) years.

2.6 Requirements for Licensing the Designation of Conformity Assessment Bodies:

Product	Designation Area	Verification Procedures	Mandatory Application	Fees (SAR) Designation/Renewal
Food	Examination and analysis of products	Imported and locally manufactured products are examined and analyzed at the expense of the importer, the manufacturer, or any party in the product supply chain	Mandatory as per the risk assessment	(1,000)
Feed	Examination and analysis of products	Imported and locally manufactured products are examined and analyzed at the expense of the importer, the manufacturer, or any party in the product supply chain	Mandatory as per the risk assessment	(1,000)
Drug	Examination and analysis of pharmaceutical preparations	Imported and locally manufactured products are examined and analyzed at the expense of the importer, the manufacturer, or any party in the product supply chain	Mandatory as per the risk assessment	(1,000)
Tobacco	Examination and analysis of imported products	Imported products are examined and analyzed at the expense of the importer	Analysis of each product in the consignment	(1,000)
Cosmetic Products	Examination and analysis of imported products	Imported and locally manufactured products are examined and analyzed at the expense of the importer, the manufacturer, or any party in the product supply chain	Mandatory as per the risk assessment	(1,000)
Medical Devices and Supplies	Examination and analysis of products	Imported and locally manufactured products are examined and analyzed at the expense of the importer, the manufacturer, or any party in the product supply chain	Mandatory as per the risk assessment	(1,000)

Note:

* SFDA collects SAR (300) for the issuance of a clearance certificate based on sampling and risk assessment.
* The validity of the conformity assessment body's designation certificate is (3) three years.

2.7 Testing Conformity Assessment Bodies Designation License Requirements:

Required Documents	Details
Approval of competent authority to site licensing	The license must be valid and issued from an accredited authority in the Kingdom of Saudi Arabia.
Commercial Register	The commercial register must be valid and include an activity related to the designation area.
ISO/IEC 17025 accreditation certificate and accreditation annex issued by competent body	• Submitting an accreditation certificate issued by the Saudi Accreditation Center (SAAC) only in the areas of accreditation. • A detailed statement of the accreditation area obtained by the body indicating the date of accreditation and the country.
Bank Guarantee	Providing a bank guarantee of SAR (200,000) for the Saudi Food and Drug Authority throughout the validity of the designation license.
Organizational structure and list of technical and administrative staff data	Include the following: • National ID, curriculum vitae, certificates of academic qualifications, practical experience, and job description of the technical staff. • A letter of undertaking the validity of the data and informing SFDA in the event of a change in the technical or administrative staff.
Laboratory details of policy, security and confidentiality of information	• Details of the laboratory's policy and procedures for maintaining the security and confidentiality of information obtained or created during the performance of its duties, and details of its arrangements to ensure that its management and employees carry out their duties in an independent, objective, ethical and impartial manner, and avoid any conflict of interests.
Laboratory quality management manual	A copy of a manual describing the laboratory's quality management procedures.
Detailed statement of approved testing and products covered by scope of testing	• A detailed statement of the approved or outsourced testing in the laboratory and the products covered by the scope of testing according to the list of testing published on the SFDA's website (here), for study and approval according to the table below:

2.7 Testing Conformity Assessment Bodies Designation License Requirements:

<table>
<tr><th>Required Documents</th><th>Details</th></tr>
<tr><td></td><td>
<table>
<tr><th>SN</th><th>Area</th><th>Product</th><th>Testing availability (internal / external)</th><th>Testing</th><th>Price (SAR)</th><th>Approved / unapproved</th><th>External laboratory</th><th>Country</th></tr>
</table>
</td></tr>
<tr><td>Agreements with external laboratories</td><td>The contract concluded with the external laboratory and copies of the laboratory accreditation and the extent of its coverage of the testing area.</td></tr>
<tr><td>Liability insurance policy for the conformity assessment body</td><td>A valid insurance policy that covers professional errors during the practice of conformity assessment works issued from an entity approved by the Central Bank of Saudi Arabia.</td></tr>
</table>

- Payment of the designation fees.
- After fulfilling the requirements, the designation certificate is issued through GHAD System in the required designation area for a validity period of (3) three years.

2.8 Conditions and requirements for procedures of renewing/ updating designation certificate for conformity assessment bodies and testing conformity assessment bodies:

What applies to the version applies to the renewal, in addition to complying with the following:

1. Submitting the application to SFDA at least (3) three months prior to the expiration date of the designation certificate, and the renewal must be from the expiration date of the previous certificate.
2. Updating the designation certificate of the conformity assessment bodies by adding a new area/or country /or testing does not change the validity date of the basic certificate (first version).

2.9 Periodic assessment of designated body:

The performance of the designated body must be subject to an annual periodic assessment by SFDA and must be based on the following points:

1. Periodic review of the designated body's information, and maintaining the scope of accreditation.
2. Recommendations of the SFDA's representatives participating in the committee charged with maintaining impartiality and the committees of complaints, appeals and disputes of the designated body.
3. Carrying out inspection visits to ensure that the bodies comply with the designation regulation and the SFDA's other requirements related to the designation areas.
4. Assessment visits periodically conducted by SFDA and in exceptional cases when complaining or appealing the technical competence of the designated body. The complaint or appeal must be officially submitted and supported by justifications.
5. Delays recorded in the implementation of the conformity assessment works entrusted to the designated body according to the agreed periods.

03
General Provisions

1. Complying with all laws and regulations of conformity assessment works and the regulation of conformity assessment bodies designation.
2. Complying with the provision of conformity assessment services to issue the conformity certificates entrusted to it, in accordance with the conditions set forth in the laws and the latest update of the regulations.
3. The conformity assessment body must not provide any qualification services and/or consultations and/or internal audits to its customers.
4. Complying with maintaining the insurance policy renewal annually.
5. The body must freely study all technical files of the products that SFDA refers to. The body may provide technical justifications when it is unable.
6. In the event that workshops are held for categories of importers, SFDA must be coordinated with.
7. Maintaining accreditation in the designation area. In the event that the accreditation is updated, SFDA must be informed.
8. Updating its information annually, which was submitted during the first submission to SFDA, including accreditation.
9. SFDA must be notified immediately in the event of suspension of accreditation.
10. Ensuring the participation of the SFDA's representative as a permanent member in the impartiality committees and the committees of examining complaints, appeals and disputes related to business specified in the designation area.
11. Accepting the assessments conducted by SFDA to assess its performance, for example: field assessment works, attending meetings and works of its committees.
12. Complying with responding to the reports of inspection visits and providing SFDA with corrective plans using the approved forms within the prescribed period.
13. Maintaining records and documents of nonconformities that are detected during the designation and follow-up works in the designation area, provided that this includes at least all information on establishments, quantities and other

information of importance, and complying with informing SFDA in writing or electronically if SFDA so requests.

14. Full cooperation during the visit and provision of all facilities and means that help the team perform its missions.

15. Coordinating joint visits with the SFDA's inspectors (if SFDA so requests) to ensure that the conformity assessment bodies implement the SFDA's requirements and to ensure the validity of the procedures for issuing conformity certificates in the country of origin, provided that the conformity body bears all the visit costs.

16. Not issuing or bringing any conformity certificates of any of the products, services, or operations, prohibited in Saudi laws and regulations, to the Kingdom of Saudi Arabia.

17. The designated body must bear full legal liability for all reports issued by it that are proven to be incorrect and the consequent damage, financial expenses and penalties as a result of nonconformities as approved by SFDA. The body has the right to object and submit a statement.

18. Complying with starting the designation works only after the issuance of the designation certificate by SFDA.

19. Complying with cooperating with SFDA within the framework of coordinating the exchange of information to unify and develop conformity assessment procedures set forth in the relevant regulations and evidence.

20. The conformity assessment body or the testing conformity assessment body must comply with the electronic linking with the SFDA's systems as issued by SFDA in this regard and/or providing a direct way to log into the system of the designated body and notifying SFDA if the system does not operate or is changed.

21. An acknowledgment by the body to comply with and apply the conditions set forth in the laws and technical regulations of SFDA and to maintain the conditions of confidentiality, impartiality and non-discrimination in all designation works delegated to it by SFDA.

22. Complying with paying the fees due to SFDA within a period not exceeding (60) sixty days from the issuance date of invoices, whether for invoices of

certificates and/or analysis reports issued electronically or on paper. In the event of non-compliance with payment, the legal actions set forth in the regulation of conformity assessment bodies designation will be taken.

23. Not assuming SFDA any faults that may occur by the applicant in the designation area.

24. The conformity body or the importer does not have the right to demand that the product be cleared in the event that the registration or listing of the product has been cancelled by SFDA.

25. Undertaking to follow up on all updates issued by SFDA to the laws, regulations, conditions, requirements, circulars and instructions, and any amendments or additions that are made and published on the SFDA's website.

04
Annex

4.1 Technical Annex to Certification and Inspection Reports on Guidance on the Requirements of Designation of Conformity Assessment Bodies

Purpose

This technical annex applies to:

01 Certificates of conformity for food and/or cosmetic consignments	02 Certificates of conformity for food and/or cosmetic products
03 Quality management systems certificates	04 Inspection reports

To clarify the technical conditions and requirements for the conformity assessment bodies to carry out the missions assigned to them in verifying, certification and monitoring of establishments to ensure the safety, quality and compliance of products and consignments with the SFDA's conditions and requirements.

First: Conditions and requirements for issuing certificates:

1. Food products conformity certificate

Requirements and Standards
The food product must meet all the requirements set forth in the technical regulations and all the supplementary references referred to in the technical regulations approved by SFDA, including the regulations shown below, in addition to the circulars published on the SFDA's website: 1. Labeling Of Prepackaged Food Stuffs. GSO9 2. Expiration Dates For Food Products – Part 1: Mandatory Expiration Dates. SFDA.FD/GSO 150-1 3. Expiration Dates For Food Products - Part 2: Voluntary Expiration Dates. SFDA.FD/GSO 150-2 4. HYGIENIC REGULATIONS FOR FOOD PLANTS AND THEIR PERSONNEL. GSO/21 5. Additives Permitted For Use In Food Stuffs. SFDA.FD/GSO 2500 6. Requirements of Nutritional Labeling. SFDA.FD 2233

7. Requirements For Nutrition And Health Claim In The Food. SFDA.FD 2333 8. Microbiological Criteria for Foodstuffs. SFDA.FD/GSO 1016 9. Maximum Limits Of Pesticide Residues in Agricultural and Food Products. SFDA.FD 382 10. HALAL FOOD - Part 1: General Requirements. SFDA.FD/GSO 2055-1 11. Maximum Residues Limits (Mrls) Of Veterinary Drugs in Food. SFDA.FD/GSO 2481 12. Extraction Solvents and its Residue Limits In The Production Foodstuffs And Food Ingredients. SFDA.FD/GSO 2359 13. Contaminants and Toxins in Food and Feed. SFDA.FD CAC 193 14. General Requirements for Handling of Foods for Special Medical Purposes. SFDA.FD/GSO 1366 15. SFDA.FD/GSO 2106 Infants Formula, Follow on Formula and Formulas for special medical purposes 16. General Requirements for Transportation and Storage of Chilled and Frozen Foods SFDA.FD/GSO 323

Processes and production lines to be audited and inspected		
Required activities	**Product assessment**	**Product assessment The conformity body must:** - Assess the entire technical file of the concerned product according to the requirements and criteria described above. - Assess the establishment's compliance with applying the technical standards and regulations approved by SFDA.
	Quality management system audits within establishment:	- The conformity body must audit the establishment and issue ISO/IEC 22000 Quality Management System Certificate or HACCP Certificate as a minimum for quality systems. - Quality management systems certificates (HACCP) are accepted as a minimum, which are submitted by the customer to the conformity verification body as part of meeting the requirements of Saudi Food and Drug Authority, as described in the guidance

	Inspection	**The conformity body must:** - Inspect for the purpose of sampling for testing. - Inspect to meet the requirements and standards of SFDA and issue inspection reports.

Sampling and Frequency

The sampling must be conducted by the conformity body, in accordance with the technical regulations approved by SFDA as part of meeting the SFDA's requirements as described in the guidance, ensuring that the sample is traced to the production line.

List of testing to be passed by product

All testing set forth in the technical regulations and circulars of the product issued by SFDA.

Accreditations required to carry out these activities

1. ISO/IEC 17020 for establishment inspections and sampling for testing.
2. ISO/IEC 17025 for testing and sampling analysis.
3. ISO/IEC 17065 for issuing conformity certificates.
4. ISO/IEC 17021 for auditing quality management systems.

Required competence of technical staff of conformity assessment body

A bachelor's degree in one of the following majors or equivalent: microbiology, general biology, arthropods and parasites, molecular and cellular biology, mycology, biochemistry, virology, chemistry, organic chemistry, analytical chemistry, inorganic chemistry, chemical engineering, materials engineering, environmental sciences, environmental health sciences, environmental protection, food processing engineering, nutrition and food sciences, medical microbiology, environment engineering, therapeutic nutrition, plant production and protection, horticulture and crops, veterinary medicine, food sciences, and human nutrition.

Information required for conformity certificate

According to the forms approved by SFDA, which include the trader name, commercial register number, establishment details (establishment address, production line location, license number, expiration date of the license), standard references and technical standards, country of origin, and product information (product name, item name, trademark, certification date, expiration date of the certificate, reference to the certificate agreement between the certification body and the certificate holder, production sites and/or assessments carried out, reference of the accreditation or recognition status of the conformity assessment body, and legally binding signature of the authorized signatory on behalf of the conformity assessment body and these requirements as a minimum.

Registration and listing			
The conformity body must: 1. Ensure that the product conforms to the laws, technical regulations, and requirements approved by SFDA. 2. Examine the technical documents submitted for the purpose of registering the product in the SFDA's electronic systems. 3. Comply with any additional circulars, resolutions, or requirements issued by SFDA.			
Conditions required for clearance			
Meeting and applying the food clearance conditions published on the SFDA's website at the following link: https://www.sfda.gov.sa/sites/default/files/202111/SFADF102021aa.pdf to products that will be granted a conformity certificate, while keeping records documenting the conformity audit of such requirements by SFDA and submitting them to the conformity body.			
Reviewing assessment results and issuing certificate		Conformity assessment body	
Scope of certificates		For local and imported products	
Certificate validity period		1. (1) one year from the issuance date for the following food products: (food additives, food for nutritional and medical uses, food for infants and children and energy drinks). 2. (3) three years from the issuance date for the rest of the food products.	
Periodic surveillance	**1st Year**	**2nd Year**	**3rd Year**
Market samples testing or examining	As per the risk assessment	Surveillance 1	As per the risk assessment
Factory samples inspection and testing	As per the risk assessment	As per the risk assessment	As per the risk assessment
Quality management system audits in addition to random tests or inspections	Surveillance 1	Surveillance	Recertification

2. Consignments Conformity Certificates for Food Products

Requirements and Standards
The food product must meet all the requirements and supplementary references referred to in the technical regulations approved by SFDA, including the regulations shown below, in addition to the circulars published on the SFDA's website: 1. SFDA.FD/GSO 323 General Requirements for Transportation and Storage of Chilled and Frozen Foods. 2. GSO 9 Labeling of Prepackaged Food Stuffs. 3. SFDA.FD/GSO 2106:2021 Infants Formula, Follow on Formula and Formulas for special medical purposes. 4. SFDA.FD/GSO 150-1 Expiration Dates for Food Products -Part 1: Mandatory Expiration Dates. 5. SFDA.FD/GSO 150-2 Expiration Dates for Food Products - Part 2: Voluntary Expiration Dates. 6. SFDA.FD/GSO 2500 Additives Permitted for Use in Food Stuffs. 7. SFDA.FD 2233 Requirements of Nutritional Labeling. 8. SFDA.FD 2333 Requirements for Nutrition and Health Claim in The Food. 9. SFDA.FD 1016 Microbiological Criteria for Foodstuffs. 10. SFDA.FD 382 Maximum Limits of Pesticide Residues in Agricultural and Food Products. 11. SFDA.FD/GSO 2055-1 HALAL FOOD - Part 1: General Requirements. 12. SFDA.FD/GSO 2481 Maximum Residues Limits (Mrls) Of Veterinary Drugs in Food. 13. SFDA.FD/GSO 2359 Extraction Solvents and its Residue Limits in The Production Foodstuffs and Food Ingredients. 14. SFDA.FD CAC 193 Contaminants and Toxins in Food and Feed. 15. SFDA.FD/GSO 1366 General Requirements for Handling of Foods for Special Medical Purposes.

<table>
<tr><th colspan="3">Processes to be inspected</th></tr>
<tr><td>Required activities</td><td>Inspection</td><td>The conformity body must:
- Conform the documents based on the clearance conditions and requirements.
- Ensure that the product conforms to the regulations and standards set forth in the clearance conditions for each product.
- Ensure that the consignments conform to the clearance conditions and requirements for the products subject to the SFDA's supervision.
- Inspect and ensure the safety and conformity of the means of transport and containers to the SFDA's requirements and they are stamped with the seal of the conformity verification office on the lock of the container and/or means and/or batch of transport.
- Inspect for the purpose of sampling for testing.</td></tr>
<tr><th colspan="3">Sampling and Frequency</th></tr>
<tr><td colspan="3">"Sampling must be conducted by the conformity assessment body for testing, in accordance with the technical regulations approved by SFDA and ensure that the sample is tracked, so that it represents the consignment, provided that the consignment for which the conformity certificate is required to be issued is seized to ensure that the products in the consignment are not changed and stamped with the seal of the conformity verification office on the lock of the container and/or means and/or batch of transport".</td></tr>
<tr><th colspan="3">List of testing to be passed by product</th></tr>
<tr><td colspan="3">According to the food testing list, the minimum acceptable level of food testing for consignment certificates of conformity.</td></tr>
<tr><th colspan="3">Accreditations required to carry out these activities</th></tr>
<tr><td colspan="3">1. ISO/IEC 17020 for consignment inspections and sampling for testing.
2. ISO/IEC 17025 for testing and sampling analysis.
3. ISO/IEC 17065 for certification processes.</td></tr>
</table>

Required competence of technical staff of conformity assessment body

A bachelor's degree in one of the following majors or equivalent: microbiology, general biology, arthropods and parasites, molecular and cellular biology, mycology, biochemistry, virology, chemistry, organic chemistry, analytical chemistry, inorganic chemistry, chemical engineering, materials engineering, environmental sciences, environmental health sciences, environmental protection, food processing engineering, nutrition and food sciences, medical microbiology, environment engineering, therapeutic nutrition, plant production and protection, horticulture and crops, and veterinary medicine.

Information required for conformity certificate

According to the forms approved by SFDA, which include the customer's name and address, name and address of the certification body, invoice number, container number, exporter name, country of export, product details (product name, manufacturing date, expiration date, batch number, weight and country of manufacture), certificate issuance date, sites of assessment and/or assessments carried out, reference of the accreditation or recognition status of the conformity assessment body, and legally binding signature of the authorized signatory on behalf of the conformity assessment body, reference number and issuance date of the conformity certificate, and these requirements as a minimum.

Registration and listing

The conformity body must verify:

The registration of the product in the SFDA's electronic systems, according to the approved laws, regulations, standards, and circulars issued by SFDA.

Conditions required for clearance

The consignment certificate of conformity must include a statement by the certification body that the consignment meets the requirements and conditions for food clearance published on the SFDA's website, including means of transport, storage, quantities received, batches, conformity of documents, and mandatory requirements for clearance.

Reviewing assessment results and issuing certificate	Conformity assessment body.
Scope of certificates	For imported products.
Certificate validity period	Expires by clearing the consignment.

3. Cosmetic products conformity certificates

Requirements and Standards		
The product must be in conformity with the technical regulations shown below, in addition to the specified product standard and any other requirements that are communicated via circulars and announcements of the Saudi Food and Drug Authority: 1. Executive regulation of cosmetic products law (here). 2. SFDA.CO/GSO 1943. 3. SFDA.CO/GSO 2528. 4. ISO/IEC 22716 – Good Manufacturing Practices for Cosmetics. 5. Guidance on controls and requirements for listing cosmetic products. 6. Lists of banned and restricted cosmetic ingredients, colorants, preservatives, and UV filters (here). 7. Circulars published on the SFDA's website (here).		
Processes and production lines to be audited and inspected		
Required activities	**Product assessment**	**The conformity body must:** 1. Assess the cosmetic product information file (PIF) according to SFDA.CO 6000 and in accordance with the requirements and standards described above. 2. Assess the establishment's compliance with applying the technical standards and regulations approved by SFDA.
	Quality management system audits within establishment	- The conformity body must audit the establishment and issue a quality system certificate (GMP) as a minimum for quality systems or equivalent, in accordance with the requirements and standards described above. - The quality system certificate (GMP) is accepted as a minimum for quality systems or equivalent, which is submitted by the customer to the conformity verification body as part of meeting the SFDA's requirements as described in the guidance.
	Inspection	**The conformity body must:** - Inspect for the purpose of sampling for testing. - Inspect to meet the SFDA's requirements and standards and issue inspection reports.

Sampling and Frequency

Sampling must be conducted by the conformity assessment body for testing and ensure that the sample is tracked, so that it is similar to the production line, in accordance with the mechanism approved by SFDA for sampling and risk criteria.

List of testing to be passed by product

List of cosmetic testing for consignment conformity certificates.

Accreditations required to carry out these activities

1. ISO17020 for establishment inspections and sampling for testing.
2. ISO17025 for testing and sampling analysis.
3. ISO17065 for issuing conformity certificates.
4. ISO17021 for auditing quality management systems in accordance with ISO/IEC 22716 - Good Manufacturing Practices for Cosmetics.

Required competence of technical staff of conformity assessment body

A bachelor's degree in one of the following majors or equivalent: pharmacy, pharmaceutical sciences, pharmaceutical care, epidemiology, preventive health, chemistry, biochemistry, toxicology, pharmacology, health promotion, health security, virology, and preventive medicine and public health.

Information required for certificate of conformity

According to the forms approved by SFDA, which include the trader name, commercial register number, establishment details (establishment address, production line location, license number, expiration date of the license), standard references and technical standards, country of origin, and product information (product name, item name, trademark, listing reference number, certification date, expiration date of the certificate, reference to the certificate agreement between the certification body and the certificate holder, production sites and/or assessments carried out, reference of the accreditation or recognition status of the conformity assessment body, and legally binding signature of the authorized signatory on behalf of the conformity assessment body and these requirements as a minimum.

Registration and listing

The conformity body must verify that:

1. The product conforms to the laws and technical regulations, standards and requirements approved by SFDA.
2. The technical documents submitted for the purpose of listing the product in the SFDA's electronic systems are examined.

Acknowledgments required from establishment
1. An acknowledgment by the customer not to be relieved from the obligations and responsibilities on the product after being registered/ listed. 2. An acknowledgment by the customer of the validity of all information submitted to the conformity body. 3. Reviewing and applying the cosmetic clearance conditions published on the SFDA's website to the products/consignment that will be granted a certificate of conformity, and keeping records documenting the conformity audit of such requirements.

Conditions required for clearance
Meeting and applying the food clearance conditions published on the SFDA's website at the following link: https://www.sfda.gov.sa/sites/default/files/2022-03/SFDA-Cosmetic.pdf to products that will be granted a conformity certificate, while keeping records documenting the conformity audit of such requirements by SFDA and submitting them to the conformity body.

Responsibility for reviewing assessment results and issuing certificate		Responsibility for reviewing assessment results and issuing certificate	
Scope of certificates		Scope of certificates	
Certificate validity period		Certificate validity period	
Periodic surveillance	1st Year	2nd Year	3rd Year
Market samples testing or examining	As per the risk standards for cosmetic products	As per the risk assessment	As per the risk assessment
Factory samples inspection and testing	As per the risk assessment - as per the risk standards for cosmetic products	As per the risk assessment	As per the risk assessment
Quality management system audits (GMP)	According to the requirements of ISO/IEC 17021 and in accordance with ISO/IEC 22716 - Good Manufacturing Practices for Cosmetics.		

4. Consignment conformity certificates for cosmetic products

<table>
<tr><th colspan="3">Requirements and Standards</th></tr>
<tr><td colspan="3">The product must be in conformity with the technical regulations below, in addition to the specified product standard and any other requirements that are communicated via circulars and announcements of the Saudi Food and Drug Authority:
1. Executive regulation of cosmetic products law (here).
2. SFDA.CO/GSO 1943.
3. SFDA.CO/GSO 2528.
4. ISO/IEC 22716 – Good Manufacturing Practices for Cosmetics.
5. Lists of banned and restricted cosmetic ingredients, colorants, preservatives, and UV filters (here).
6. Circulars published on the SFDA's website (here).
7. Conditions for clearing cosmetic products and the raw materials used in their manufacture.</td></tr>
<tr><td colspan="3">Processes to be inspected</td></tr>
<tr><td>Required Activities</td><td>Inspection</td><td>The conformity body must:
1. Ensure that the product is registered in the SFDA's systems.
2. Ensure that the product conforms to the actual import.
3. Ensure the physical integrity of the product.
4. Conform documents based on the clearance conditions and requirements.
5. Ensure that the product conforms to the regulations and standards set forth in the clearance conditions for each product.
6. Ensure that the consignments conform to the clearance conditions and requirements for the products subject to the SFDA's supervision.
7. Inspect and ensure the safety and conformity of the means of transport and containers to the requirements of SFDA and stamped with the seal of the conformity verification office on the lock of the container and/or means of transport and/or batch.
8. Inspect for the purpose of sampling for testing.</td></tr>
<tr><td colspan="3">Sampling and Frequency</td></tr>
<tr><td colspan="3">Sampling must be conducted by the conformity assessment body for testing and ensure that the sample is tracked, so that it is similar to the consignment sent, in accordance with the mechanism approved by SFDA for sampling and risk criteria.</td></tr>
</table>

List of testing to be passed by product
Unless SFDA issues a provision of the regulation that are required to be applied to the products for which a conformity certificate is to be issued and the required analyses, the testing must be conducted in accordance with (list of cosmetic testing). The conformity body has the right to add what it deems appropriate to verify the conformity of the products to the technical regulations, standards, and circulars issued by SFDA.
Accreditations required to carry out these activities
ISO/IEC 17020 / ISO/IEC 17025 for sampling and analysis. ISO/IEC 17065 for certification processes.
Required competence of technical staff of conformity assessment body
A bachelor's degree in one of the following majors or equivalent: pharmacy, pharmaceutical sciences, pharmaceutical care, epidemiology, preventive health, chemistry, biochemistry, toxicology, pharmacology, health promotion, health security, virology, preventive medicine and public health, and microbiology.
Information required for certificate of conformity
Trader name, commercial register number, invoice number, container number, exporter, country of export, product details (product date, expiration date, batch number, weight, quantity, country of manufacture and product name), listing reference number, inspector's name and signature, certificate number and date, production sites and/or assessments carried out, reference of the accreditation or recognition status of the conformity assessment body, and these requirements as a minimum.
Registration and listing
The conformity body must verify that: The product is listed in the SFDA's electronic systems, according to the approved laws, regulations, standards, and circulars issued by SFDA.
Acknowledgments required from the establishment
An acknowledgment by the customer not to be relieved from product obligations and responsibilities after being registered/listed. An acknowledgment by the customer of the validity of all information submitted to the conformity body.

Conditions required for clearance	
Meeting and applying the clearance conditions published on the SFDA's website at the following link: https://www.sfda.gov.sa/sites/default/files/2022-03/SFDA-Cosmetic.pdf to products that will be granted a conformity certificate, while keeping records documenting the conformity audit of such requirements by SFDA and submitting them to the conformity body.	
Responsibility for reviewing assessment results and issuing certificate	Conformity assessment body.
Scope of certificates	For imported products.
Certificate validity period	Expires once the consignment is cleared at the port.

5. Food Safety Management Systems Certificate (ISO/IEC 22000)

Requirements and Standards		
ISO/IEC 22000 and the references mentioned in the standard.		
Processes and production lines to be audited and inspected		
Required activities	**Quality management system audits within the establishment:**	The conformity body must audit the establishment and all its facilities, food plant, or slaughterhouse, including production lines, and issue a Food Safety Management Certificate (ISO/IEC 22000) in accordance with the above-mentioned requirements and standards.
	Inspection	The conformity body must: Conduct inspections of the establishment and sampling for analysis and testing.
Accreditations required to carry out these activities		
1. ISO/IEC 17020 for establishment inspections and sampling for analysis and testing. 2. ISO/IEC 17021 for auditing quality management systems in accordance with ISO/IEC 22000.		
Required competence of technical staff of conformity assessment body		
A bachelor's degree or its equivalent in one of the following majors: food sciences and human nutrition, food processing engineering, microbiology, mycology, biochemistry, environmental sciences, environmental health sciences, environmental protection, medical microbiology, and veterinary medicine.		

Information required for conformity certificate
Establishment details (establishment name, establishment address, production line, inspection date, certificate number and certificate expiry date).

Acknowledgments required from the establishment			
1. An acknowledgment by the customer not to be relieved from product obligations and responsibilities after being registered/listed. 2. An acknowledgment by the customer of the validity of all information submitted to the conformity body.			
Reviewing assessment results and issuing certificate	Conformity assessment body.		
Certificate validity period	(3) three years from the issuance date.		
Periodic surveillance	**1st Year**	**2nd Year**	**3rd Year**
Market samples testing or examining	As per the risk assessment.		
Factory samples inspection and testing			
Quality management system audits in addition to random tests or inspections	According to the requirements of (ISO/IEC 17021).		

6. Certificate of Good Manufacturing Practices for Cosmetic Products (GMP)

Requirements and Standards
1. The approved laws, regulations, standards, and circulars issued by SFDA. 2. Guidance on Good Manufacturing Practices for Cosmetic Products (GMP). 3. ISO/IEC 22716 – Good Manufacturing Practices for Cosmetics.
Processes and production lines to be audited and inspected
The conformity body must verify the following: 1. The establishment complies with applying the standards and technical regulations approved by SFDA. 2. The establishment obtained the good manufacturing practices for cosmetic products (GMP) as a minimum standard for quality systems. 3. Inspection to meet the SFDA's requirements and issue an inspection report.

Required activities	**Quality management system audits within the establishment:**	- The conformity body must audit the establishment and issue a certificate of Good Manufacturing Practices for Cosmetic Products (GMP) as a minimum standard for quality systems in accordance with the above-mentioned requirements and standards. - The conformity body must verify that the establishment complies with applying the standards and technical regulations approved by SFDA.
	Inspection	The conformity body must conduct inspections of the establishments and sampling for analysis and testing.

List of testing to be passed by product

All tests set forth in the technical regulations and circulars issued by SFDA.

Accreditations required to carry out these activities

ISO/IEC 17020 for establishment inspections and sampling for testing
ISO/IEC 17025 for testing and sample analysis.
ISO/IEC 17021 for auditing quality management systems in accordance with ISO/IEC 22716- Good Manufacturing Practices for Cosmetics.

Required competence of technical staff of conformity assessment body

The technical staff must have, as a minimum, a bachelor's degree or its equivalent in one of the following majors: pharmacy, pharmaceutical sciences, pharmaceutical care, epidemiology, preventive health, chemistry, biochemistry, toxicology, pharmacology, microbiology, health promotion, health security, virology, preventive medicine, public health, and pharmaceutical management.

Information required for conformity certificate

Establishment details (establishment name, establishment address, production line, inspection date, certificate number and certificate expiry date).

Responsibility for reviewing assessment results and issuing certificate	Conformity assessment body.		
Certificate validity period	(3) three years from the issuance date.		
Periodic surveillance	**1st Year**	**2nd Year**	**3rd Year**
Quality management system auditsFactory samples inspection and testing	According to the requirements of (ISO/IEC 17021).		

7. Certificate of quality management system for establishments of medical devices and supplies (ISO/IEC 13485)

Requirements and Standards
- The medical devices and supplies law and its executive regulation, and the quality management system compatible with the latest version of "ISO 13485 Medical Devices - Quality Management Systems - Regulatory Requirements". - Requirements for inspection and quality management system for medical devices and supplies (MDS-REQ10).
Processes and production lines to be audited
Plants and establishments for medical devices and products.

Required competence of technical staff of conformity assessment body
1. The employees participating in the quality management system audit must have the knowledge, sufficient awareness, certificates, and training necessary for audit when applying the standard requirements "Medical Devices - Quality Management Systems - Regulatory Requirements - ISO (13485), in addition to general experience in the medical devices and supplies subject of designation. 2. Compliance and adherence to the technical requirements contained in the international reference issued by the International Medical Device Regulators Forum (IMDRF): "Competence and Training Requirements for Auditing Organizations" and its references. 3. The technical staff must have, as a minimum, a bachelor's degree in one of the following majors or its equivalent: biomedical engineering, medical device engineering technology, physics, nuclear physics, medical physics, nuclear engineering, nuclear engineering technology, medical microbiology, medical laboratory, biotechnology, and biochemistry.

Information required for conformity certificate			
Completing all the SFDA's requirements and requirements set forth in ISO 13485 activities and items covered by the audit.			
Reviewing assessment results and issuing certificate	Conformity assessment body.		
Certificate validity period	(3) three years.		
Periodic surveillance	**1st Year**	**2nd Year**	**3rd Year**
Quality management system audits	According to the requirements of (ISO/IEC 17021) and the requirements of the Saudi standard (SFDA.MD/GSO ISO 13485) or its equivalent.		

7. Certificate of quality management system for establishments of medical devices and supplies (ISO/IEC 13485)

Requirements and Standards
- The medical devices and supplies law and its executive regulation, and the quality management system compatible with the latest version of "ISO 13485 Medical Devices - Quality Management Systems - Regulatory Requirements". - Requirements for inspection and quality management system for medical devices and supplies (MDS-REQ10).
Processes and production lines to be audited
Plants and establishments for medical devices and products.

Required competence of technical staff of conformity assessment body
1. The employees participating in the quality management system audit must have the knowledge, sufficient awareness, certificates, and training necessary for audit when applying the standard requirements "Medical Devices - Quality Management Systems - Regulatory Requirements - ISO (13485), in addition to general experience in the medical devices and supplies subject of designation. 2. Compliance and adherence to the technical requirements contained in the international reference issued by the International Medical Device Regulators Forum (IMDRF): "Competence and Training Requirements for Auditing Organizations" and its references. 3. The technical staff must have, as a minimum, a bachelor's degree in one of the following majors or its equivalent: biomedical engineering, medical device engineering technology, physics, nuclear physics, medical physics, nuclear engineering, nuclear engineering technology, medical microbiology, medical laboratory, biotechnology, and biochemistry.

Information required for conformity certificate			
Completing all the SFDA's requirements and requirements set forth in ISO 13485 activities and items covered by the audit.			
Reviewing assessment results and issuing certificate	Conformity assessment body.		
Certificate validity period	(3) three years.		
Periodic surveillance	**1st Year**	**2nd Year**	**3rd Year**
Quality management system audits	According to the requirements of (ISO/IEC 17021) and the requirements of the Saudi standard (SFDA.MD/GSO ISO 13485) or its equivalent.		

Second: Conditions and requirements for issuing inspection reports:

1. Inspection Report (Food)

Requirements and Standards		
The approved laws, regulations, standards, and circulars issued by SFDA: - Food hygiene requirements. - Technical Regulation No. (SFDA.FD 21) "Hygienic Regulations for Food Plants and Their Personnel". - (SFDA.FD/GSO 1694) "General Rules of Food Hygiene". - Technical regulations and standards related to the food product to be exported. - Hazard Analysis and Critical Control Points (HACCP) or any equivalent system. - Best Aquaculture Practice (BAP) (for establishments exporting aquatic organisms of animal origin, the cultured aquatic organisms only).		
Processes and production lines to be inspected		
Required activities	**Inspection**	The conformity body must inspect the establishment and verify the following: - All facilities of the establishment, food plant, or slaughterhouse, including production lines, are in accordance with the above-mentioned "Requirements and Standards".
Sampling and Frequency		
Sampling must be conducted by the conformity body, and ensure that the sample is tracked, so that it is similar to the production line, if the same is requested by the Saudi Food and Drug Authority.		

List of testing to be passed by product
All tests stipulated in the technical regulations, and circulars issued by SFDA, if the same is requested by the Saudi Food and Drug Authority.
Accreditations required to carry out these activities
1. ISO/IEC 17020 for establishment inspections and sampling for testing. 2. ISO/IEC 17025 for testing and sample analysis.
Required competence of conformity assessment body
A bachelor's degree or its equivalent in one of the following majors: food sciences and human nutrition, food processing engineering, microbiology, mycology, biochemistry, environmental sciences, environmental health sciences, environmental protection, medical microbiology, and veterinary medicine

Information required for the report
1. A report showing the establishment's application of the "Requirements and Standards". 2. Report of nonconformities with the images, specifying the risk of each nonconformity (high risk, medium risk and low risk). 3. Preparing a video report on the entire establishment. 4. Preparing a special report on the source of raw materials used in manufacturing. 5. A special report on monitoring residues and contaminants.
Acknowledgments required from the establishment
1. An acknowledgment by the customer not to be relieved from product obligations and responsibilities after being registered/listed. 2. An acknowledgment by the customer of the validity of all information submitted to the conformity body.
Assessment results reviewing and making recommendations
A recommendation issued by the conformity assessment body, provided that it is approved by the Saudi Food and Drug Authority.

2. Inspection Report (cosmetic)

Requirements and Standards		
1. The approved laws, regulations, standards, and circulars issued by SFDA. 2. Guidance on Good Manufacturing Practices for Cosmetic (GMP). 3. ISO/IEC 22716 - Good Manufacturing Practices for Cosmetic.		
Processes and production lines to be inspected		
Required activities	**Inspection**	The conformity body must inspect the establishment and verify the following: 1. The establishment complies with applying the standards and technical regulations approved by SFDA. 2. The good manufacturing practices for cosmetic (GMP) are applied as a minimum standard for quality systems. 3. Meeting the SFDA's requirements and issuing an inspection report.
Accreditations required to carry out these activities		
ISO/IEC 17020 for establishment inspections in accordance with the above-mentioned requirements and standards.		

Required competence of conformity assessment body
The technical staff must have, as a minimum, a bachelor's degree or its equivalent in one of the following majors: pharmacy, pharmaceutical sciences, pharmaceutical care, epidemiology, preventive health, chemistry, biochemistry, toxicology, pharmacology, microbiology, health promotion, health security, virology, preventive medicine, public health, and pharmaceutical management.
Information required for the report
A report signed by the inspection team that includes the following details: Establishment name, establishment address, production line, inspection date and term, inspection team members, summary of establishment activities and premises, the observations detected with a classification of their severity with the reference and the guidance on the good manufacturing practices for cosmetic, the recommendation and the inspection summary, and a list of the persons present during the inspection.
Assessment results reviewing and making recommendations
Saudi Food and Drug Authority.

4.2 Additional Annex

1. GHAD System Link (SFDA).
2. The SFDA's standards and regulations online store (here) and gulf standards store GSO. (here)
3. List of minimum approved designation testing. (here)
4. Guidance on the conditions for clearing cosmetic products and the raw materials used in their manufacture. (here)
5. Mechanism of approving the official regulators and establishments in countries wishing to export food products to the Kingdom of Saudi Arabia.
6. Conditions and requirements for importing foodstuffs into the Kingdom of Saudi Arabia.
7. Conditions and requirements for food clearance.
8. Obligation to obtain a conformity certificate according to the food item and the country.
9. Food safety requirements published on the SFDA's website.
10. Hazard criteria for cosmetic products published on the SFDA's website.
11. Cosmetic products testing.
12. Guidance on registration and listing.
13. Requirements for licensing establishments of medical devices and supplies MDS - REQ 9
14. Inspection requirements and quality management system of medical devices and supplies MDS - REQ 10.
15. Conditions and requirements for clearing tobacco products.
16. Guidance on plain packaging of tobacco products.
17. List of acceptable minimum food testing for consignment conformity certificates. (here)
18. List of cosmetic testing for consignment conformity certificates. (here)
19. Guidance on licensing the practice of activity for conformity verification bodies and the quality management system and quality assurance for medical devices and supplies.

For contact and inquiries:
Contact the SFDA's Call Centre on 19999

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