Global Certification and Monitoring Services

GCMS system certification scheme

CS-01

GENERAL

Management system certification is used to provide confidence that organization's management system fulfils specified requirements. To perform a system conformity assessment, certification body is adopting a scheme that defines three major parts of the conformity assessment. Firstly, the objects of conformity assessment including the specific scope where the client's activity belongs to the (group of) products/services and their aspects and the involved parties. Secondly, specified requirements, specific rules and procedures apply. Finally, the methodology of performing the conformity assessment according to the accreditation standards; the quality management manual of the certification body and the adopted certification process.

SCOPE

The document identifies the scheme of management system conformity assessment, for different scopes listed in the annex, including the objects of conformity assessment, the specified requirements for the object of conformity assessment and the methodology for performing conformity assessment.

The scheme is developed by the scheme owner *Global Certification Monitoring Services* to share it with all its clients, that are willing to get management system certificate and to ensure their awareness about the requirements certification process

REFERENCES

- ISO/IEC 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems.
- CASCO brochure: How to develop scheme documents - Guidance for ISO technical committees – Edition 1 (2019).

SCHEME

1. Objects of system's conformity assessment

- Scope description: The specific category from the different groups of sectors classified by the specific certification scheme, as listed in the annex of this document.
- Parties involved:

Client: Organizations that aim to get a system certification.

Certification body: Global Certification Monitoring Services (GCMS)

Accreditation body: Egyptian Accreditation Council (EGAC)

Interested parties: Customers, Independent Laboratories; National and regional regulatory agencies; Governmental and non-governmental organizations.

2. Specified requirements for the object of conformity assessment.

Following the objects of system conformity assessment identified in the previous chapter, this scheme lists below all the specified requirements related to the involved parties in the conformity assessment.

Systems' certification standards and regulations.	**ISO 9001:2015** Quality management systems — Requirements **ISO 22000:2018** Food safety management systems — Requirements for any organization in the food chain **ISO/TS 22002 series** Prerequisite programmes on food safety **FSSC 22000 V6.0** Certification Scheme for Food Safety Management Systems **ISO 45001:2018** Occupational health and safety management systems — Requirements with guidance for use **ISO 14001:2015** Environmental management systems — Requirements with guidance for use

	ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes **ISO 37001:2025** Anti-bribery management systems — Requirements with guidance for use **ISO/IEC 27001:2022** Information security, cybersecurity and privacy protection — Information security management systems — Requirements
Requirements for certification body	**ISO/IEC 17021-1:2015** Conformity assessment — Requirements for bodies providing audit and certification of management systems Part 1: Requirements. **ISO 19011:2018** Guidelines for auditing management systems **ISO/IEC 17021-2:2016** Conformity assessment — Requirements for bodies providing audit and certification of management systems Part 2: Competence requirements for auditing and certification of environmental management systems. **ISO/IEC 17021-3:2017** Conformity assessment — Requirements for bodies providing audit and certification of management systems Part 3: Competence requirements for auditing and certification of quality management systems. **ISO/IEC 17021-9:2016** Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 9: Competence requirements for auditing and certification of anti-bribery management systems **ISO/IEC TS 17021-10:**2018 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 10: Competence requirements for auditing and certification of occupational health and safety management systems **ISO 22003-1:2022** Food safety Part 1: Requirements for bodies providing audit and certification of food safety management systems **FSSC 22000** Scheme Food Safety Management System Certification Version 6.0 (April 2023) **ISO/IEC 27006-1** Information security, cybersecurity and privacy protection — Requirements for bodies providing audit and certification of information security management systems — **IAF MD 22:2019** Application of ISO/IEC 17021-1 for the certification of occupational health and safety management systems (OH&SMS)

	IAF MD 9:2022 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485) **IAF MD 13:2023** Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001)
Legal requirements	The applicable legal requirements in the countries where the activity of the organization is located.
Accreditation body (EGAC) requirements	(R1G) Regulations to be met by conformity assessment bodies (R4G) The use of EGAC accreditation symbol (R5G) Accreditation Process Time Limitations and Response Actions to Findings of CABs
Quality Management System at GCMS.	(QMS 01) Procedure of management of competencies (QMS 02) Sampling Mechanism (QMS 04) Audit time calculation procedure (QMS 05) Procedure of management of impartiality (QMS 06) Procedure of Non-conformities Identification and Management (QMS 07) Complaints and appeals management process (QMS 08) Documents and records control procedure (QMS 09) Personnel duties, responsibilities and authorities (QMS 10) Rules for use of logo, certificates and marks of conformity (QMS 11) Procedure of Granting, Termination, reduction, suspension or withdrawal of certification (QMS 12) Internal audit procedure (QMS 13) Management Review Procedure (QMS 15) System certification procedure (QMS 16) Operating procedure for GCMS subsidiaries (QMS 17) Outsourcing mechanism (QMS 18) Terms of Reference for Internal Committees and Units (QMS 19) Quality Manual

3. Methodology for performing management system conformity assessment.

This part is generalized and applicable to all product/service categories adopted by *Global Certification Monitoring Services* group. The scheme follows the functional approach of conformity assessment which consist of the following parts: Selection, Determination, Review, Decision, Attestation and Surveillance.

- SELECTION

  Application: The client, willing to get management system certificate, should apply through *Global Certification Monitoring Services* group website, filling all necessary information related to the company and other documents upon request.

  The Client shall pay the fees of certification and shall sign the agreement between his company and *Global Certification Monitoring Services (GCMS)*.

  Application review: GCMS certification manager performs the application review, assign the convenient team according to their competency (QMS-01) as well as the category of the product and decides whether to accept the application or not.

  In case of accepting the application, the invoice for certifications fees is sent to the client to be paid. Then, an agreement for certification services is signed between GCMS and the client stating the different legal obligations for both parties.

  Audit program: Following the information provided by the client, GCMS certification manager establish the audit time and develop an audit program. According to the requirements, the audit program list all the audit categories planned for the client during the current year (Certification, Surveillance, etc..) with approximate dates. This document also identifies other important information like audit scope, audit objectives, specific audit criteria and scheme, audit team. Depending on the nature of the system to be certified, a sampling process could be developed and planned

before on-site audit (QMS-02). When part of the system is outsourced, the evidence of the subcontractor compliance to the requirements are requested and an extra audit may be conducted. The audit program should consider the specific requirements in case the client is applying for multi-sites management system and/or integrated management system.

Audit plan: After communication with the client, the audit team fix a date and the time for conducting the audit. The audit plan indicates the client information, scope of the audit, audit criteria, audit objectives, audit time, all audit participants, and a detailed agenda of the audit day. The audit plan is sent to the client one week before the audit date.

- DETERMINATION

Conducting the audit: The first initial certification audit is conducted on-site for some categories with shorter duration, and it consists of auditing the client according to the general requirements. This stage helps in checking the readiness of the client's system to be certified, if it is the case, stage 2 audit is conducted with deep checking and following all the requirements.

The audit process follows the procedures of *Global Certification Monitoring Services (GCMS*) and the requirements of accreditation standards. A formal opening meeting should be held with the management of the Client and the main departments' representatives involved in the system. The purpose of this meeting, which is conducted by the head of the audit team, is to explain the objectives of the audit and the audit process. After that, the audit starts with the first part: the review of documents using sampling method to collect information and evidence about the compliance of client's system with the requirements of the declared standards. The second part is the observation of the premises and organization site with possibility of conducting and interview with personnel. For both parts of the audit, different type of evidences is collected by auditors in total transparency with the client representative to use them later in the audit report.

Audit results: The audit team meets separately to discuss the collected evidences by each auditor, to identify and classify audit results and summarize them in one document. Audit findings are classified in three parts: Good practices, Opportunities

for improvement (Recommendations) and Non-conformities description with the related clause from audit criteria. All discrepancies found are discussed with the Client to ensure that the evidence collected is accurate and that the details of the discrepancy are clear to the Client. At the same time, the auditors do not comment or suggest the reasons for the inconsistencies and do not propose solutions to correct the inconsistencies found.

Closing meeting; A formal closing meeting, considering all participants, should be held with the management of the organization and the representative of its departments involved in the system. The purpose of this meeting, which is conducted by the audit team lead, is to present the audit findings including an explanation of the non-conformances found. The closing meeting includes a notification to the client that the evidence collected during the audit is based on sampling method, thus considering the element of uncertainty; the time frame for the client's provision of a plan for the implementation of measures to eliminate non-conformities discovered during the audit; Information on the complaints and appeals process and other steps prior certification.

- REVIEW

  Audit report: The audit team provides the client with a written report on each audit. The report form is following the accreditation requirements, and it describes the conformity assessment status of the client for each chapter of the certification standards with detailed description of the evidence collected.

  Audit conclusion will summarize the total status of conformity of the client towards management system certification standards and provide the final recommendation of auditors. In addition to that, the report mentions if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future surveillance audits) will be needed to verify effective correction and corrective actions.

  Before the end of the agreed period, the client shall ensure that all the non-conformances detected in the audit were fully removed. The audit team review and approve the measures implemented to eliminate non-conformances and

their effectiveness. After that, the audit team makes new recommendations for a certification decision based on the gathered evidence.

- DECISION

  The decision-maker assigned at GCMS headquarter reviews all information and results related to the evaluation as well as the recommendation on the certification provided by the auditors. Decisions on granting, suspension, revocation, and refusal of certification, as well as expanding or reducing the scope of certification are made following the requirements of ISO/IEC 17021-1 and GCMS procedure (QMS-11).

- ATTESTATION

  Management system certificate: If all certification requirements are fulfilled and a positive decision on the provision of certificate is made, GCMS issues the management system certificate to the Client. The Certificate is issued with a unique identification number for each client.

  Usage of Certificate and Logo: Rules for use of logo, certificates and marks of conformity at GCMS is following the procedure (QMS-10). The Client is forbidden to use Management System Standard's logo on the product's labels. If the customer misuses the GCMS Group logo and/or the issued Certificate, the Certificate may be suspended or cancelled. In the absence of immediate corrective actions from the Client's side, GCMS appeals to the District Court of the relevant country.

- SURVEILLANCE

  The activity of the Client must be constantly monitored. The onsite audits must be conducted as often as it is specified in the Certification Agreement (at least once a year) giving due regard to the requirements of the certification standard to which the certification has been conducted, type of the non-conformances detected, any complaints received from the client. Regular surveillance audits are carried

out on the same principle as certification audits, but the audit duration can be much shorter, depending on the complexity of the audited organization, the results of previous audits and the established frequency of surveillance audits.

Changes Affecting Certification: The certification requirements are established through the properly published certification standards, and the Certification Scheme. If the requirements of the standards or their interpretations change, GCMS Group's Clients will be informed through the GCMS website and by writing emails. From client's side, the changes affecting certification shall be approved of upon request by the client. Unapproved changes discovered during surveillance activities (these changes are treated as non-conformances). GCMS certification manager reviews all change requests in accordance with the appropriate procedures and standards. It then evaluates all applicable documents detailing the changes and makes the appropriate decision regarding the certification.

Reduction, Suspension or Withdrawal of Certification: Following GCMS procedure (QMS-11) for Granting, Termination, reduction, suspension or withdrawal of certification, in a case of minor breaches found during the surveillance audits the Client shall be presented with an official warning and given certain amount of time to eliminate the breach. If the breaches are not eliminated, the certificate is withdrawn, and the Client is forbidden to use the GCMS Group logo.

In a case of a very serious breach found during the audit, the certificate is withdrawn immediately, and the Client is immediately forbidden to use the GCMS Group's logo. In a case of suspension or revocation of the certificate, the client is obliged to return the original copy of the issued certificate (including all Annexes to the Certificate) to the relevant GCMS subsidiary by registered mail within 10 (ten) business days.

If Certification is terminated (by request of the Client), suspended or withdrawn, the relevant GCMS subsidiary takes actions specified in the appropriate documents and makes all necessary modifications to formal certification documents, public information, authorization for the use of logo, etc., to ensure it provides no indication that the system is continued to be certified.

If a scope of certification is reduced, the relevant GCMS subsidiary takes actions specified by appropriate documents and makes all necessary modifications to formal certification documents, public information, authorization for the use of logo, etc., to ensure the reduced scope of certification is clearly communicated to the Client and is clearly specified in certification documentation and public information.

If certification is reinstated after suspension, the relevant GCMS subsidiary makes all necessary modifications to formal certification documents, public information, authorization for the use of logo, etc., to ensure all appropriate indications, exist that the organization continues to be certified.

If a decision to reduce the scope of certification is made as a condition of reinstatement, GCMS makes all necessary modifications to formal certification documents, public information, authorization for the use of logo, etc., to ensure the reduced scope of certification is clearly communicated to the Client and is clearly specified in certification documentation and public information.

Complaints and Appeals: GCMS Group has a documented procedure (QMS 07) for the management of complaints and appeals directed to any of GCMS subsidiaries which provides the requirements for the recording and tracking of complaints and appeals and actions to resolve them. The Complains and Appeals Committee is responsible for addressing complaints and appeals. GCMS Group is dedicated to the satisfactory resolution of complaints and appeals.

CRITERIA FOR SCHEME REVIEW AND VALIDATION

Scheme is developed according to the current accredited categories at Global Certification Monitoring Services (GCMS). The scheme is reviewed after any changes in the accreditation categories, or in the objects of conformity assessment, or in the requirements of conformity assessment or the methodology for performing conformity assessment. This current version, all changes and upcoming updates are approved by GCMS top management.

Annex

Scope of certification per standard

- **ISO 22003-1:2022 Categories**

Cluster	Category	Subcategory	
Primary production	**A** Farming or handling of animals	AI	Farming of animals for meat/milk/ eggs/honey
		AII	Farming of fish and seafood
	B Farming or handling of plants	BI	Farming – Handling of plants (other than grains and pulses)
		BII	Farming – Handling of grains and pulses
		BIII	Pre-process handling of plant products
Processing food for humans and animals	**C** Food, ingredient and pet food processing	C0	Animal – Primary conversion
		CI	Processing of perishable animal products
		CII	Processing of perishable plantbased products
		CIII	Processing of perishable animal and plant – Products (mixed products)
		CIV	Processing of ambient stable products
	D	Feed and animal food processing	
	E	Catering/food service	
Retail, transport and storage	**F** Trading, retail and e-commerce	FI	Retail/ wholesale
		FII	Brokering/ trading
	G	Transport and storage services	
	H	Services	
Packaging material	**I**	Production of packaging material	
Auxiliary equipment	**J**	Equipment	
Bio/chemical	**K**	Chemical and bio-chemical	

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Cat.	Sub-cat.	Description
B	BIII	Pre-process handling of plant products
C	C0	Animal – Primary conversion
	CI	Processing of perishable animal products
	CII	Processing of perishable plant-based products
	CIII	Processing of perishable animal and plant products (mixed products)
	CIV	Processing of ambient stable products
D	D	Processing of feed and animal food
E	E	Catering / food service
F	FI	Retail / Wholesale / E-commerce
	FII	Brokering / Trading / E-commerce
G	G	Transport and storage services
I	I	Production of packaging material
K	K	Production of Bio-chemicals

- **ISO 9001 codes (from IAF MD17)**

Technical cluster	IAF CODE	Description of economic sector/activity, according to IAF ID1
Food	1	Agriculture, forestry and fishing
	3	Food products, beverages and tobacco
	30	Hotels and restaurants
Mechanical	17	Basic metals and fabricated metal products
	18	Machinery and equipment
	19	Electrical and optical equipment
	20	Shipbuilding
	22	Other transport equipment
Paper	7	Limited to "Paper products"
	8	Publishing companies
	9	Printing companies
Minerals	2	Mining and quarrying
	15	Non-metallic mineral products
	16	Concrete, cement, lime, plaster, etc.
Construction	28	Construction
	34	Engineering services
Goods production	4	Textiles and textile products
	5	Leather and leather products
	6	Wood and wood products
	14	Rubber and plastic products
	23	Manufacturing not elsewhere classified
Chemicals	7	Limited to "Pulp and paper manufacturing"
	10	Manufacture of coke and refined petroleum products
	12	Chemicals, chemical products and fibres
Supply	25	Electricity supply
	26	Gas supply
	27	Water supply
Transport & Waste management	24	Recycling
	31	Transport, storage and communication
	39	Other social services
Services	29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods
	32	Financial intermediation; real estate; renting
	33	Information technology
	35	Other services
	37	Education
	36	Public administration
Nuclear	11	Nuclear fuel
Pharmaceutical	13	Pharmaceuticals
Aerospace	21	Aerospace
Health	38	Health and social work

- **ISO 14001 codes (from IAF MD17)**

Technical cluster	IAF CODE	Description of economic sector/activity, according to IAF ID1
Agriculture, forestry and fishing	1	Agriculture, forestry and fishing
Food	3	Food products, beverages and tobacco
	30	Hotels and restaurants
Mechanical	17	Basic metals and fabricated metal products
	18	Machinery and equipment
	19	Electrical and optical equipment
	20	Shipbuilding
	21	Aerospace
	22	Other transport equipment
Paper	7	Limited to "Paper products"
	8	Publishing companies
	9	Printing companies
Construction	28	Construction
	34	Engineering services
Goods production	4	Textiles and textile products
	5	Leather and leather products
	6	Wood and wood products
	23	Manufacturing not elsewhere classified
Chemicals	7	Limited to "Pulp and paper manufacturing"
	10	Manufacture of coke and refined petroleum products
	12	Chemicals, chemical products and fibres
	13	Pharmaceuticals
	14	Rubber and plastic products
	15	Non-metallic mineral products
	16	Concrete, cement, lime, plaster, etc.
	17	Limited to "Base metals production"
Minerals	2	Mining and quarrying
Supply	25	Electricity supply
	26	Gas supply
	27	Water supply
Transport & Waste management	24	Recycling
	31	Transport, storage and communication
	39	Other social services
Services	29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods
	32	Financial intermediation; real estate; renting
	33	Information technology
	35	Other services
	37	Education
	36	Public administration

Nuclear	11	Nuclear fuel
Health	38	Health and social work

- **ISO 45001 codes from (IAF MD17)**

Technical cluster	IAF CODE	Description of economic sector/activity, according to IAF ID1
Agriculture, forestry and fishing	1	Agriculture, forestry and fishing
Food	3	Food products, beverages and tobacco
	30	Hotels and restaurants
Mechanical	17	Basic metals and fabricated metal products
	18	Machinery and equipment
	19	Electrical and optical equipment
	20	Shipbuilding
	21	Aerospace
	22	Other transport equipment
Paper	7	Limited to “Paper products”
	8	Publishing companies
	9	Printing companies
Construction	28	Construction
	34	Engineering services
Goods production	4	Textiles and textile products
	5	Leather and leather products
	6	Wood and wood products
	23	Manufacturing not elsewhere classified
Chemicals	7	Limited to “Pulp and paper manufacturing”
	10	Manufacture of coke and refined petroleum products
	12	Chemicals, chemical products and fibres
	13	Pharmaceuticals
	14	Rubber and plastic products
	15	Non-metallic mineral products
	16	Concrete, cement, lime, plaster, etc.
	17	Limited to “Base metals production”
Minerals	2	Mining and quarrying
Supply	25	Electricity supply
	26	Gas supply
	27	Water supply
Transport & Waste management	24	Recycling
	31	Transport, storage and communication
	39	Other social services
Services	29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods

	32	Financial intermediation; real estate; renting
	33	Information technology
	35	Other services
	37	Education
	36	Public administration
Nuclear	11	Nuclear fuel
Health	38	Health and social work

- **ISO 13485 Technical Areas (From IAF MD 9)**

Main Technical Areas	IAF Code	Technical Areas
1.1 Non-active Medical Devices	1.1 A	General non-active, non-implantable medical devices
	1.1 B	Non-active implants
	1.1 C	Devices for wound care
	1.1 D	Non-active dental devices and accessories
	1.1 E	Non-active medical devices other than specified above
1.2 Active Medical Devices (Non-Implantable)	1.2 A	General active medical devices
	1.2 B	Devices for imaging
	1.2 C	Monitoring devices
	1.2 D	Devices for radiation therapy and thermo therapy
	1.2 E	Active (non-implantable) medical devices other than specified above
1.3 Active Implantable Medical Devices	1.3 A	General active implantable medical devices
	1.3 B	Implantable medical devices other than specified above
1.4 In Vitro Diagnostic Medical Devices (IVD)	1.4 A	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
	1.4 B	In Vitro Diagnostic Instruments and software
	1.4 C	IVD medical devices other than specified above
1.5 Sterilization Method for Medical Devices	1.5 A	Ethylene oxide gas sterilization (EOG)
	1.5 B	Moist heat
	1.5 C	Aseptic processing
	1.5 D	Radiation sterilization (e.g. gamma, x-ray, electron beam)
	1.5 E	Low temperature steam and formaldehyde sterilization
	1.5 F	Thermic sterilization with dry heat
	1.5 G	Sterilization with hydrogen peroxide
	1.5 H	Sterilization method other than specified above
	1.6 A	Medical devices incorporating medicinal substances

1.6 Devices Incorporating / Utilizing Specific Substances / Technologies	1.6 B	Medical devices utilizing tissues of animal origin
	1.6 C	Medical devices incorporating derivates of human blood
	1.6 D	Medical devices utilizing micromechanics
	1.6 E	Medical devices utilizing nanomaterials
	1.6 F	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
	1.6 G	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above.
1.7 Parts or Services	1.7 A	Raw materials
	1.7 B	Components
	1.7 C	Subassemblies
	1.7 D	Calibration services
	1.7 E	Distribution services
	1.7 F	Maintenance services
	1.7 G	Transportation services
	1.7 H	Other services