

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

**MALAWI BUREAU OF STANDARDS
QUALITY ASSURANCE SERVICES DEPARTMENT
CERTIFICATION AND INSPECTORATE DIVISION**

Bottled Drinking Water Certification Scheme

In accordance with MS 560:2004 Natural mineral water-specification
and MS 699:2004 Bottled drinking waters other than natural mineral water –
Specification.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

1. Introduction

- 1.1. This product certification Scheme outlines the framework for certifying bottled drinking water based on the requirements of ISO/IEC 17067 and the national standards MS 560:2004 Natural Mineral Water-specification and MS 699:2004 Bottled drinking water other than natural mineral water. This scheme ensures product compliance, safety, and quality in line with the aforementioned Malawi standards as mandated by the Malawi Bureau of Standards Act (51:02) and MBS Certification Marks Regulations (2016).
- 1.2. The MBS-CID is, therefore, deemed the scheme owner in terms of ISO/IEC 17067 "Conformity assessment - Fundamentals of product certification and guidelines for product certifications schemes".

2. Scope

This certification scheme applies to all producers of bottled drinking water seeking certification under MS 560:2004 and MS 699:2004. It covers product pre-requirements, application, evaluation, conformity assessment, and continuous surveillance of certified products.

3. Normative References

The following documents are indispensable for the application of this certification scheme:

- a) ISO/IEC 17065: Conformity assessment-Requirements for bodies certifying products, processes and services,
- b) ISO/IEC 17067: Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes,
- c) Malawi Bureau of Standards Act (2013),
- d) MBS Certification Marks Regulations (2016),
- e) MS 560:2004 Natural mineral water-specification,
- f) MS 699:2004 Bottled drinking water other natural mineral water-specification,
- g) MS 21:2002 Food and food processing units-code of hygienic conditions, and
- h) MS 19:2024 Labeling of foods-general standard.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

4. Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17067 and the referenced national standards apply.

5. Certification Scheme Type

5.1. This scheme adopts ISO/IEC 17067:2013 Type 5 certification, which includes type testing, assessment and approval of the quality management system, follow-up surveillance including testing of samples from the factory and/or the open market, and periodic audits of the production process.

5.2. The scheme includes the following functions, activities and elements.

a) Selection including:

- specified requirements for the products covered by the scope of the scheme,
- elements of the production process to be assessed and of the management system to be audited,
- determination activities, and the basis on which those activities be undertaken,
- sampling methods and frequency,
- requirements which the applicant/licensee has to fulfil in order to gain and maintain certification of the product, and
- any other certification requirements.

b) Determination includes conformity assessment activities such as:

- Testing of the product based on MS 560:2004 for natural mineral water and MS 699:2014 for bottled drinking water other than natural mineral water.
- Inspection of the product packaging and labeling based on MS 19:2024 Packaging and labeling-general standard.
- assessment of the production process and audit of other elements of the client's quality control system critical to managing product conformity through document review and onsite assessment based on MS 21:2002 Food and food processing units-code of hygienic conditions.

c) Review of the evaluation results for the production process and, or product, making certification decision, and attestation of conformity based on the review that fulfilment of specified requirements have been demonstrated.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

d) Licensing and control of the mark including:

- mark of conformity,
- publicity to applicants/licensees,
- misuse of certification and marks of conformity;

e) Surveillance: this certification scheme includes:

- testing and inspection of product samples,
- assessment of the production process and audit of the quality control system,
- suspending and withdrawing a certification and license, and
- managing changes affecting certification.

6. Requirements for product

The requirements for the product specified in this product certification scheme are given in the Malawi Standard No. 560: 2004 *Natural mineral water-specification* and MS 699:2004-*Bottled drinking waters other than natural mineral water – Specification*.

7. Certification Process

The certification process includes the following steps:

7.1. Pre-requirements

7.1.1. Registration

An organization that intends to be certified on the MBS-CID bottled drinking water scheme shall have completed the registration process with the Registrar of Business and Malawi Revenue Authority for Tax payment.

7.1.2. Verification

MBS-CID reserves the right to verify the authenticity of any documents submitted by the applicant during the registration.

7.1.3. Conformance/Compliance

Before making application, the organization shall ensure that it meets the requirements of this product certification scheme for both the product and production processes.

7.2. Application

7.2.1. MBS CID shall provide the applicant with all information necessary to understand and follow the rules for this certification scheme. These rules shall be publicly

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

available. Application for certification shall be made on the prescribed form MBS-CID-P800-F01.

7.2.2. Application Review

- a) Once the application is received from the applicant, MBS-CID shall confirm that the information provided by the applicant is clear and sufficient and, if not, shall request the applicant for the necessary clarification or additional information.
- b) MBS-CID shall confirm that the applicant is registered and approved under the MBS product certification scheme. If this has been satisfactorily achieved, the applicant shall be subject to the MBS-CID certification processes which involve evaluation of the bottled water and auditing of the quality and production system of the applicant. In the event that MBS-CID has rejected the client application, the Deputy Director of Quality Assurance Services (DDQAS-CID) shall formally write to the client stating the reasons.
- c) The client shall be required to complete the MBS-CID Certification Agreement Form MBS-CID-P100-F01 if the review outcome shows that the application is accepted.

7.3. Evaluation

7.3.1. Evaluation plan

- a) From the information provided in the application, MBS-CID shall confirm that it has the competence and capability to undertake the certification activities or not.
- b) MBS-CID shall prepare an evaluation plan setting out:
 - confirmation of the product for which certification is sought– i.e. natural mineral water or bottled drinking waters other than natural mineral water;
 - confirmation of the requirements standard i.e. MS 560:2004 or MS 699:2004;
 - the evaluation methods and procedures to be used where these are not specified in the standards;
 - the product samples and/or the sampling procedures required for evaluation;
 - the methods and procedures to be used when assessing the production process;
 - the coverage and the extent of the auditing of the management system;
 - the personnel and other resources, including outsourcing, to be used for the evaluation.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

- c) After confirmation of the acceptance of the application, MBS-CID shall make the necessary arrangements with the applicant for the initial assessment in accordance with the evaluation plan.
- d) Under this certification scheme, the following determination activities are used; initial testing and examination of the product, assessment of the production process, and audit of the elements of the quality control (management) system that are critical to product conformity.
- e) The certification body (MBS-CID) shall be responsible for all actions included in the certification scheme, including sampling, testing, assessment of the production process, auditing of the management system, and surveillance of the certified product.

7.3.2. Initial product evaluation

- a) The product evaluation shall be carried out by MBS-CID in accordance with the methods specified in MS 560:2004 and MS 699:2004 and with the procedures specified by this scheme.
- b) MBS-CID testing facilities used in product evaluation shall meet the technical requirements of ISO/IEC 17025:2005 for the product being certified.

7.3.3. Assessment of the production processes

- a) The applicant shall designate a responsible person as the main contact with the certification body; and a person(s) with management responsibility for the technical performance of the production processes and management system.
Note: this could be the same person.
- b) The initial assessment of the production process shall include assessment through direct observation and examination of the production line and communicating with production personnel to demonstrate:
 - that the applicant has the necessary facilities, equipment, personnel and procedures for carrying out the tasks associated with producing bottled drinking waters in accordance with the requirements of MS 560:2004 and MS 699:2004 and this product certification scheme. The applicant shall have an internal laboratory or have access to a laboratory suitably equipped and staffed, where those tests given in MS 560:2004 or MS 699:2004 shall be carried out in accordance with the methods given in the standards,
 - records of tests and inspection shall be kept in suitable forms. Copies of any records and other connected papers that may be required by MBS-CID shall be made available at any time on request,

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

- that the applicant shall have the capability and competence to monitor, measure and test the product during and after production so as to assure conformity with the specific product requirements of MS 560:2004 or MS 699:2004 and this product certification scheme,
- that the applicant sampling and testing (whether it be in-house or outsourced) is undertaken in accordance with the requirements of MS 560:2004 or MS 699:2004 and this product certification scheme,
- all the testing equipment available at the client's premises shall be periodically checked for continued suitability and records of calibration/ verification or both shall be maintained,
- awareness of taking of samples by MBS-CID and subsequent verification of test results or inspection reports by the certification body,
- quality control of the product through the production process in accordance with the requirements of MS 699:2004 and this product certification scheme, from the receipt of inputs, through all transformation processes, through to dispatch of the completed products; and
- the ability of the applicant to identify and quarantine nonconforming product and to maintain product traceability.

7.3.4. Specific requirements for product and production processes

- a) Raw water - The water used in production of bottled drinking water other than natural mineral water shall be initially tested for compliance with all chemical and biological requirements given in MS 214:2013 for drinking water and MS 733:2005 Bore hole and shall well water quality for natural mineral water. When raw water is to be transported from its source to bottling or container filling facility, the transportation shall be conducted in hygienic manner that will prevent any contamination. Where the untreated water is received from a source of portable water (for example from municipal supply), the manufacturer shall not be required to perform the tests provided the manufacturer is satisfied that its source can consistently deliver portable water.
- b) Hygienic conditions-The licensee shall follow the requirements of MS 21:2002 *Food and food processing units-Code of hygienic conditions* and MS 701:2005 *Natural mineral waters-Code of practice* in collecting, processing, handling, storage, packaging and marketing of the bottled water.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

- c) The applicant shall arrange for sampling and testing/analysis on each lot of bottled drinking water as given in MS 560:2004 or MS 699:2004.

7.3.5. Packing

- a) Packaging of bottled drinking water shall be done in accordance with requirements provided in MS 560:2004 or MS 699:2004. Packed product shall be stored away from direct sunlight. Bottled water shall not be packaged in secondary (used) containers.
- b) Packaged bottled drinking water shall be held for 48 hours before dispatch so as to ensure that it conforms to all the requirements applicable for "each lot".

7.3.6. Marking

Marking shall be done in accordance with MS 19:2024, MS 560:2004 or MS 699:2004 including;

- Name of the product "Natural mineral water" including its brand name
- Net contents by volume
- Lot identification
- Best before date
- Name and address of the manufacturer
- Country of origin
- Instruction for Storage
- Chemical composition
- Location and name of source
- Carbonation

7.4. Use of MBS-CID Standardization Mark

The MBS-CID product certification logo shall be used as given in MBS-CID-P200-Procedure for use of license, certificate and mark of conformity. The standard number (i.e. MS 560) shall be included in the MBS-CID logo. (Only after certification approval). Misuse of MBS-CID Certification logo shall result in corrective action or withdrawal of certification as per MBS-CID-P200.

- 7.5. **Lot**–For the purpose of this Scheme, the quantity of packaged bottled drinking water treated/processed from same raw water source and filled/packed in one day shall constitute a lot or batch. The decision regarding conformity or otherwise of the lot/batch to the given requirement shall be made based on the basis of tests and analysis of the test results.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

7.6. **Nonconforming product**

7.6.1. The applicant or client shall maintain a separate record providing detailed information regarding nonconforming lots and mode of their disposal. Such product shall in no case be stored together with conforming product.

7.6.2. Microbiological Requirements

When a failure is noticed in any of the microbiological requirements in a lot during in-process quality control, the lot shall not be dispatched. Any previous lots available in stock shall be dispatched into the market only after rechecking. The applicant/certificate holder shall reject the entire previous defective stock if the stock is found noncompliant.

7.6.3. Whenever, the quality of processed water is found not meeting the requirements of MS 560:2004 and MS 699:2004, the source of water shall be retested for such parameters in which failure is observed in order to determine the necessary controls to be exercised for conformance of quality of processed water. If the retest results are not meeting the requirements, the lot shall be handled as a nonconforming product.

7.6.4. The certificate holder shall take immediate corrective actions, which involve complete investigation of the reasons for contamination and nonconformity. The manufacturer shall re-start marking and dispatch the products only after the completion of satisfactory corrective actions and availability of satisfactory results of all microbiological tests as applicable for each control unit, for next three consecutive lots. The original frequency of dispatch after 48 hours shall be restored, if all the three lots are found conforming to the microbiological requirements. The manufacturer shall keep complete records of such instances for review by MBS CID.

7.6.5. Subsequently, the quality of the water may be regularly assessed at least once in three months through in-house testing for Colour, Odour, Taste, and Turbidity, pH, Total Dissolved Solids and Microbiological requirements. In addition, any other requirements as considered necessary for process control, are to be tested where the incidence of their presence in higher levels has been detected during the previous tests.

7.6.6. In case non-conformity is observed for radioactive residues, the source of raw water shall be abandoned.

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

7.7. Management system

7.7.1. Elements of a management system covered in an audit shall be the elements of the quality control (management) system critical for product conformity and shall include review of:

- a) procedures covering production processes, including quality control, production resources and personnel competence that can affect product conformity;
- b) documents and records control in relation to production processes and product conformity;
- c) existing management system certifications and associated audit reports;
- d) internal audits and management reviews;
- e) procedures and records associated with product non-conformance, corrective and preventive actions;
- f) the identification, marking, and marketing of conforming products in accordance with certification requirements and certificate agreements;
- g) those management system processes that are carried out by the client as part of the product certification scheme; and
- h) that the client has the necessary planned arrangements to ensure that the management system processes will continue to be effectively implemented and maintained.

7.7.2. It is recommended that, as far as possible, Statistical Quality Control (SQC) methods be used for controlling the quality of the product during production as envisaged in this scheme. In addition, efforts should be made to gradually introduce a Management System in accordance with ISO/MS 9001 or ISO/MS 22000.

8. Certification Decision

The decision to grant certification is made by the certification body based on evaluation of audit findings, test results, and compliance with MS 560:2004 and MS 699:2004. The decision is made by personnel independent of the evaluation. If successful, a certificate is issued and maintained through regular surveillance.

9. Attestation and licensing

- 9.1. Upon successful evaluation, the certification body issues an attestation of conformity confirming that the product meets the requirements of MS 560:2004 or MS 699:2004. The attestation serves as evidence of product compliance.
- 9.2. Following attestation, a license to use the MBS-CID certification mark is granted to the manufacturer. The license outlines the terms and conditions for using the

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

mark on certified bottled drinking water products and is valid for three (3) years subject to surveillance.

10. Surveillance

- 10.1. MBS-CID shall develop a surveillance plan for the certificate holders and shall conduct surveillance in order to provide confidence that products manufactured after the initial certification fulfil the specified requirements.
- 10.2. Surveillance activities shall cover all sites where manufacturing takes place and shall include the following:
 - a) Inspection of product samples taken at least once from the factory and also the market to determine fulfilment with the requirement at the point of production and continued compliance of the product in the distribution chain, respectively.
 - b) Assessment of the production processes and auditing of the management system, including examination of the client's quality records relating to the production process,
 - c) In the event that the certified products and or production process fail, the surveillance and testing frequency shall be increased. The frequency shall be reverted to two (2) times in a year if the consecutive test results are found to be meeting the standard requirements.
 - d) MBS-CID shall carry out tests on characteristics (not done in routine and periodic analysis) as occasional analysis. The occasional analysis shall be done at least once in 1 year or as per request by the relevant authorities.

11. Other requirements

- 11.1. If there is change in source of raw water, the certificate holder shall formally advise MBS-CID.
- 11.2. Treated water shall be analyzed at the laboratories that fulfills compliance with the requirements of ISO/IEC 17025 and commissioning of the new source for production and marking shall only be done after MBS-CID has formally approved the new source.

12. Complaints against the certified products

- 12.1. Whenever a complaint is received soon after the products with MBS-CID Mark have been purchased and used, and if there is adequate evidence that the products have not been misused and the complaint is proved to be genuine and the warranty period (where applicable) has not expired, the defective products shall be replaced free of cost by the certificate holder. The final authority to

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

judge conformity of the product to the Malawi standard shall be with MBS-CID. The certificate holder shall also have its own complaint investigation system and shall formally inform MBS-CID of any complaint received and the investigations and resolutions made.

- 12.2. In the event of any damages caused by the products bearing the certification mark, or claim being filed by the consumer against MBS-CID Standardization Mark and not “conforming to” the relevant Malawi Standards, entire liability arising out of such nonconforming products shall be of certificate holder and MBS-CID shall not in any way be responsible in such case(s).

13. Suspension of the use of the Standardization Mark

- 13.1. Marking of a product shall be stopped under instruction of MBS-CID if, at any time there is a problem in maintaining the conformity of the product to the specification. The marking may be resumed as soon as the defects are removed under formal approval by MBS-CID. The marking of the product shall be stopped immediately if directed so by MBS-CID for any reason as provided in certification agreement and procedure for use of license, certificate and mark of conformity.
- 13.2. The marking may then be resumed only after permission is given by MBS-CID. Information regarding resumption of markings shall also be sent to MBS-CID.

14. Complaints and Appeals

- 14.1. Upon receipt of a complaint or an appeal which relates to product certification activities, the MBS shall deal with it in accordance with MBS’s complaints and appeals procedure (MBS-CID-P940).
- 14.2. Where the complaint or appeal relates to the on-going non conformity of a product certified by MBS-CID, the remedial actions may involve recalling non-compliant products in which case documented evidence of such a recall shall be required.
- 14.3. Full details of the MBS-CID Complaints and Appeals procedure are available as part of the publically available information.

15. Certification fees

- 15.1. The clients under the MBS-CID Product Certification Scheme shall be liable to the upfront payment of the initial assessment and Annual certification fees unless the client/certificate holder has been approved for a credit by MBS Finance Department. The initial certification (cost of product evaluation, production facility auditing and certificate fees) shall be as given on the MBS-CID fee

Document Type:	ISO 17065 Certification Scheme	Document Number	MBS-CID-PCS001
Revision number	00	Effective date	31 st December 2024

schedule. Upon attaining certification, the certified organization shall continue to meet the charges for testing, production facility audit and certificate fees.

- 15.2. The MBS-CID shall calculate the fees based on Annual Turnover submitted by the client by 31st January of each year.

16. Responsibilities of the Client

Certified organizations are required to maintain conformity with applicable standards, cooperate with the certification body, and inform of any changes affecting compliance with the requirements provided in this certification scheme.

17. RECORDS & FORMS

No	Record & form title	Number
17.1	None	N/A

18. RELATED PROCEDURES & GUIDELINES

No	Procedure & guideline title	Number
18.1	Procedure for use of certificates and marks of conformity	MBS-CID-P200
18.2	Procedure for receipt, review and registration of application	MBS-CID-P800
18.3	Procedure for grant of certification	MBS-CID-P820
18.4	Procedure for surveillance	MBS-CID-P830
18.5	Procedure for recertification	MBS-CID-P840
18.6	Procedure for termination, reduction, suspension or withdrawal of certification	MBS-CID-P920

19. DOCUMENT HISTORY

Rev	Description of change	Effective date
00	New document	31/12/2024