1. INTRODUCTION

The scheme provides requirements for certification of disinfectants alcohol-based hand sanitiser according to the product requirements NAMS/SANS 490:2020 - Disinfectant alcohol-based handrub, the WHO Recommendations - Guide to Local Production: WHO-recommended Handrub Formulations and the Government Notice No.114 – Alcohol-based hand sanitisers regulations published in the Namibian Government Gazette (30 April 2020).

This scheme was developed in accordance to the requirements of ISO/IEC 17065: 2012 (Conformity assessment- Requirements for bodies certifying products, processes and services) and ISO/IEC 17067:2013 (Conformity assessment - Fundamentals of products certification and guidelines for product certification schemes).

2. TERMS AND DEFINITIONS

a) **Acceptable -** acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant;
b) **Bactericidal efficacy -** when the hand sanitiser is tested, it shall comply with the requirements for a hygienic handrub;
c) **Batch** - that quantity of sealed containers of hand rub that have been filled from one homogeneous blend or, in the case of a continuous production process, that have been filled from one day's production;
d) **Dermal irritation** - when the handrub is tested, it shall not irritate or inflame the skin.
e) **Certificate of conformity** – in relation to hand sanitiser, means a document issued by the NSI attesting that the safety and safety of the hand sanitiser conforms to the requirements of NAMS/SANS 490 and the WHO recommendations.
f) **CoA -** Certificate of Analysis;
g) **Defective -** sample of the handrub that fails to comply in one or more respects with relevant requirements of this standard;
h) **Disinfectant** - chemical agent that kills most vegetative forms of pathogen and other micro-organisms (but not necessarily all bacterial and fungal spores, mycobacteria, rickettsiae or viruses);
i) **Hand rub** – an alcohol-based antiseptic agent in this case have the same meaning as hand sanitiser;
j) **Hand sanitisers** - a disinfectant alcohol-based handrub referred to in NAM/SANS 490, which is an antiseptic agents used to cleanse the hands often used to protect and prevent the passage of bacteria, virus and other pathogens that can cause infections;
k) **Lot** – that quantity of handrub in sealed containers of the same size and bearing the same batch identification, from one manufacture, and submitted at any one time for inspection and testing
l) **Standard conditions** - temperature of 23 °C ± 2 °C;
m) **WHO** – World Health Organization; and
n) **%v/v –** percent volume per volume.

3. APPLICATION

Upon receipt of the application, NSI shall evaluate the application and accompanying information provided to either accept or decline an application for certification. The reasons for declining an application for certification shall be documented and be made clear to the client.

4. INITIAL INSPECTION

Once an application is approved, an initial inspection of the factory shall be conducted. The inspection shall, amongst other things;

a) Witness the production process
b) Verify that established requirements complies with the Alcohol-based hand sanitiser scheme requirements, the product standard NAMS/SANS 490 and WHO Recommendations.
c) Determine the fitness of the manufacturing premises.
d) Collect samples for testing.

All the requirements of the scheme and product standards shall be inspected during initial, surveillance and recertification inspections.

- If the inspection indicates that requirements specified in Section 5 are met and the results of the tested product conform to the requirements of **NAMS/SANS 490 and WHO Recommendations**, the NSI shall assign a product registration number, issue a certificate of conformity and NSI mark of conformity to affix on the packaging label.
- The certificate of conformity remains effective for three years, as long as the product continues to conform to the requirements and any subsequent conformity test.

5. PROCESS CONTROL

Where an organization does not operate a certified Management System (e.g. ISO 9001), the following requirements shall apply;

5.1 Production

a) Production shall be planned and carried out under controlled conditions, which shall at least include;
i. Documented information that describes characteristics for raw materials, reagents (active ingredients) and acceptance thereof. Documented information shall be retained.
ii. Documented information that describes the characteristics of the end product as per NAMS/SANS 490 and WHO Recommendations shall be maintained and retained.
iii. Documented production flow diagram and production quality control measures.
iv. Use of suitable equipment to ensure product consistency to the standard.
v. Availability and use of monitoring and measuring devices.
vi. Availability of documented work instructions.
vii. Inspection of raw materials, packaging materials and final products.

viii. The final product shall have Material Safety Data Sheet (MSDS) which provides detailed and comprehensive information of the health effects of exposure to the product, hazard evaluation related to the product's handling, storage or use, measures to protect workers or consumers at risk of exposure and the related emergency procedures.

b) The organization shall implement final product identification and traceability system.
c) Measuring equipment and devices used by the organization shall be calibrated or verified or both at specified intervals or prior to use, against measurement standards traceable to international or national standards. The organization shall retain documented information.
d) The organization shall establish specification for its packaging materials and verify their compliance against specific requirements prior to use. The organization shall retain documented information.

5.2 Formulation of hand sanitiser

a) The hand sanitiser shall be manufactured according to the following formula consistent with WHO Recommendations:
   i) Ethanol (Ethyl alcohol) 80% v/v or Isopropyl alcohol 75% v/v;
   ii) Hydrogen peroxide 0.125% v/v; and
   iii) Glycerol (glycerin) 1.45% v/v.
   iv) Deionised /distilled water

b) The handrub or hand sanitiser shall not contain any other active or inactive ingredients to improve the smell or taste, due to the risk of accidental ingestion in children or impact the quality and potency of the product.

c) The hand sanitiser shall be of a liquid or gel type, as required.

d) The Ethanol (Ethyl Alcohol) or Isopropyl Alcohol active ingredients shall be correct and the accurate amount of the active ingredient shall be used.

5.3 Nonconforming product/process

a) The organization shall establish a procedure for control of nonconforming products and processes, to ensure that nonconformities are identified and controlled to prevent their unintended use and recurrence.
b) In case of nonconformity, the organization shall take and implement effective correction and corrective action where necessary.

5.4 Corrective action

a) The organization shall establish a documented procedure for corrective action, to define requirements for:
i. Determining the causes of nonconformities;
ii. Determining the root cause of the nonconformity;
iii. Determining and implementing action needed;
iv. Reviewing the effectiveness of the corrective action taken; and

v. Evaluating the need for action to ensure that nonconformities do not recur.

b) The organization shall take action to eliminate the cause of nonconformities in order to prevent reoccurrence.

c) Records of the results of action taken shall be retained.

5.5 Factory construction, layout and conditions

The building shall be of sound construction, in good repair and large enough to allow for cleaning and the maintenance of product quality. A system of control shall be in place to keep the factory free from birds, rodents, insects and vermin, and to ensure that the product is not contaminated and product quality is not compromised.

a) Wall, floors and doors

Outer walls shall be weather proof and impervious to water. Door and door frames shall be made from corrosion-resistant material or protected to prevent corrosion. Floors shall be constructed of concrete or other durable, impermeable, non-slip material that is resistant to wear and corrosion and easy to clean with adequate drainage system.

b) Ventilation

Provision shall be made for an adequate supply of fresh air and the prevention of a buildup of toxic gases.

c) Storage facilities for finished hand sanitisers

Finished products awaiting dispatch shall be stacked, off the floor in well ventilated storage facilities. The organization shall ensure segregation of nonconforming products from conforming products.

5.6 Customer complaints

All customer complaint related to products certified under these scheme shall be recorded, investigated and records of corrective actions taken shall be retained.

5.7 Control of suppliers

The organization shall have control over incoming raw materials and packaging materials, to ensure that suppliers adhere to defined specifications. Records of Certificate of Analysis (CoA) shall be retained.

5.8 Competence

The organization shall ensure that personnel involved in the manufacturing of hand sanitiser are competent by means of training or relevant qualifications.

5.9 Third-party management system certification

a) Where an organization's Management System is certified by a recognized certification body, records indicating conformance to relevant standard shall be submitted to the NSI.

b) The NSI shall audit selected portions of the organization's management system to confirm compliance, where nonconformities are found, Section 5.1.3 shall be followed.

6. PACKAGING

The product packaging shall meet the requirements of Clause 6.1 of NAMS/ SANS 490

Units of measurements, symbols and quantities

Pre-packaged hand sanitiser must be sold in the following quantities:

a) minimum quantity of 10 mL;
b) then in integral multiples of 5mL from 10 mL up to and including 100 mL
c) then 125 mL, 150 mL, 175 mL, 200 mL, 250 mL, 300 mL, 350 mL, 375 mL, 400 mL, 450 mL, 500 mL, 750 mL, 800 mL, 1 L, 1.25 L, 1.5L, 2 L, 2.5 L, 3 L, 3.5 L, 4 L, 4.5 L, 5 L, 20 L, 25 L, and integral multiples of 1 L above 25 L.

7. LABELLING

The product labelling shall meet the requirements for Clause 6.2 of NAMS/SANS 490 and SADCMEL document 1 and 4. Each packaged product in small and/or bulk packaging shall be legibly and indelibly marked.

Table 1: Minimum height of numbers and letters

Net contents (C)	Minimum height of numbers and letters in millimeters
C ≤ 50 mL	2
50 mL < C ≤ 200 mL	3
200 mL < C ≤ L	4
1 L < C	6

8. SAMPLING

a) Samples shall be drawn at random at the manufacturer or distributor premises. The following sampling procedure shall be applied in determining whether a lot complies with the requirements of NAMS/SANS 490 and WHO Recommendations.
b) Samples will be taken and shall be deemed to represent the batch. A batch is defined as “that quantity of sealed containers of products that have been filled from one homogenous blend or, in the case of a continuous production process, that have been filled from one day’s production”.
c) Samples shall be taken in accordance with the information contained in the **Table 2** below.

Table 2: Samples for inspection and testing

Lot size number of containers	**Sample size for physical and chemical examination** *number of containers	**Sample size for micro-biological examination** number of containers
0 to 5000	3	3
5001 to 12500	6	3
12501 to 25000	9	3
25001 to 50000	16	3
50001 upwards	30	3

**Sample volume per container is equated to 250 mL.*

d) The batch shall be deemed to comply if the test results of the sampled units are satisfactory.
e) Samples shall be collected in a non-labelled and identical final product container, which will be tagged with the sample identification number.
f) A Certificate of Analysis (CoA) of the alcohol used in the formulation of the product shall be submitted together with the sample.
g) Sample collection form will be completed and signed off by both the client representative and the NSI Inspector.

9. TESTING

a) Samples for testing and visual inspection shall be collected during initial, surveillance and recertification inspection.
b) Sample(s) collected will be submitted by the NSI Inspector to the designated laboratory for analysis.
c) These samples will be analysed for the parameters given in **Table 3: Chemical analysis** and **Table 4: Physical and microbiological analysis (Bactericidal efficacy).**

Table 3: Chemical Analysis

PARAMETERS	**REQUIREMENTS**	**TOLERANCE LEVEL**
Alcohol concentration Continuous testing of finished product and records shall be maintained by the client. Compliance shall be verified during scheduled inspections.	80% v/v Ethanol (Ethyl Alcohol)	±5% v/v
	75 %,v/v Isopropyl Alcohol	±5% v/v
Alcohol presence/ identification	Ethanol (Ethyl alcohol) or Isopropyl Alcohol	N/A

Table 4: Physical and Microbiological Analysis

PARAMETERS	REQUIREMENTS
Freedom from visible impurities	Visible specks of impurities shall not exceed five. Continuous testing of finished product and records shall be maintained by the client. Compliance shall be verified during scheduled inspections.
Dermal irritation	No irritation/ inflame on skin. Continuous testing of finished product and records shall be maintained by the client. Compliance shall be verified during scheduled inspections.
Storage stability for type 1 liquid type	Store each hand sanitiser in its original unopened container under standard conditions for a period of six months, test for bactericidal efficacy and maintain records. Hand sanitiser shall comply with the requirements for bactericidal efficacy. Compliance shall be verified during scheduled inspections.
Storage stability for type 2 gel	Store each hand sanitiser in its original unopened container under standard conditions for a period of six months. Hand sanitiser shall comply with the requirements for bactericidal efficacy and shall not liquefy. Compliance shall be verified during scheduled inspections.
Bactericidal efficacy Microbiological analysis (Staphylococcus aureus, E.coli and Pseudomonas aeruginosa)	No growth. Continuous testing of finished product and records shall be maintained by the client Compliance shall be verified during scheduled inspections.

10. SURVEILLANCE INSPECTIONS

a) NSI shall conduct surveillance inspections in the first and second year after issuance of certificate of conformity at a manufacturer premises.

b) NSI shall inform the manufacturer in advance (at least a month in advance) when an inspection will be conducted.

c) Surveillance inspection shall be conducted as per inspection programme, following an inspection plan approved by the client.

d) The NSI shall collect a minimum of six (6) samples annually of each approved product from the manufacturer or distributor facility and test the samples to confirm continuous conformance with

the requirements of **Table 3** and **Table 4**. Based on the recommendations from the inspection team, the frequency of sampling may be increased.

11. RECERTIFICATION INSPECTION

a) Recertification inspection shall be conducted at the manufacture's site on the third year after the issuance of certificate of conformity.
b) NSI shall inform the manufacturer in advance (at least three months in advance) when an inspection will be conducted.
c) Recertification inspection shall be conducted as per inspection programme, following an inspection plan approved by the client.

12. ACTIONS TAKEN IN THE EVENT OF NONCONFORMITY

a. Where an inspection report indicates that the system does not comply with relevant standard and/or scheme requirements, the organization shall submit a corrective action plan within fourteen (14) working days from the last day of the inspection.
b. To verify that corrective action taken has been effective, NSI shall assess the need to conduct a special inspection and/ or test the product. The cost shall be endured by the organization.
c. If the product fails to comply with the requirements in Table 2 and 3 above, further samples shall be taken for testing.
d. In the event of non-conformity, the client shall take the necessary steps to restore conformity of the corresponding production, prevent the sale of non-conforming products and notify the Certification Body.
e. Nonconforming products shall be subjected to retesting.
f. Retested products failing to meet the specifications shall result in the suspension of the certification.
g. The certification granted may be suspended/withdrawn at any time, after the client has been informed in writing, if the requirements have not been met or maintained.

13. Reference

- Government Notice No. 114 Alcohol-based hand sanitisers regulations
- ISO 9001:2015 – Quality Management System- Requirements
- ISO/IEC 17065: 2012 - Conformity assessment – Requirements for bodies certifying products, processes and services
- ISO/IEC 17067:2013 - Conformity assessment – Fundamentals of products certification and guidelines for product certification schemes
- NAMS/SANS 490:2020 - Disinfectant alcohol-based handrub
- SADCMEL Document No. 1 - Labelling requirements for prepacked products and general requirements for the sales of goods
- SADCMEL Document No. 4 - Tolerances permitted for the accuracy of measurement made in terms of legal metrology legislation
- SANS 5261 –Bactericidal efficacy of anti-bacterial liquid toilet soap

- WHO Recommendations - "Guide to Local Production: WHO-recommended Handrub Formulations," available at https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

14. Records of revision

Revision	Date	Description
01	April 2020	Established
02	June 2020	Updated the document by adding the following information; Introduction: Government Notice No.114 Alcohol-based hand Sanitiser Regulations set out in Schedule No. 7201, in the Namibian Government Gazette (30 April 2020). Changed the numbering sequence in section 5 from 5.1.1 to 5.1 5.1 9(iv) Formulation of hand sanitiser; Deionised /distilled water 6. Packaging; Added Units of measurements, symbols and quantities 7. Labelling; TABLE 1: Minimum height of numbers and letters. 9. Testing: Table 4: Table 4: Physical and Microbiological Analysis; Added the term efficacy to bactericidal. Replaced the requirement for Low bacteria growth count with No growth.