1. Purpose

This document describes the framework to be followed by the Certification Body (CB) for the registration of locally manufactured alcohol-based hand sanitisers, as well as the approval of importing alcohol-based hand sanitisers into Namibia.

2. Definitions

- **Applicant:** the entity requesting for registration and approval of hand sanitisers, which has the same meaning as the client.
- **Attestation of Conformity:** a declaration attesting that the hand sanitiser imported into Namibia is in conformity with the requirements of NAMS/SANS 490:2020 – Disinfectant alcohol-based handrub and the provisions of the regulations.
- **Hand sanitiser:** a disinfectant alcohol-based handrub, referred to in NAMS/SANS 490, which is an antiseptic agent used to cleanse the hands so as to protect and prevent the passage of bacteria, virus and other pathogens that can cause infections.
- **Certification body:** the NSI, who is the regulator of Alcohol-based hand sanitisers.
- **Certificate of Conformity (CoC):** a document issued by the NSI attesting that the quality and safety of the hand sanitiser conforms to the requirements of NAMS/SANS 490 – Disinfectant alcohol-based handrub and the WHO recommendations.
- **Importer**: a person who imports alcohol-based hand sanitiser into Namibia.
- **Licence:** a document issued to an importer to import a hand sanitiser from a manufacturer in a country of origin of the hand sanitiser into Namibia where not mutual recognition agreement exists, as an attestation that the hand sanitiser meet the requirements of NAMS/SANS 490:2020 Disinfectant alcohol-based handrub and the provisions of the regulations.
- **Manufacturer:** an entity, including a factory that prepares, compounds or formulate hand sanitisers for consumer use as a hand disinfectant.
- **Mutual Recognition Agreement:** an agreement by which two or more countries or conformity assessment bodies agree to recognize one another's conformity assessments procedures and results.
- **Registration**: confirmation by the NSI that a hand sanitiser and manufacturing facility comply with the requirements of NAMS/SANS 490, WHO recommendations and the regulations.
- **Shall**: indicates a requirement.
- **May:** indicate a permission
- **Can:** indicate a possibility or capability

3. Acronyms

MC - Manager Certification
NSI - Namibia Standards Institution
CAC – Certification Approvals Committee
CB - Certification Body

4. Process owner

The Process Owner of this procedure shall be the **Manager: Certification (MC).**

5. Activities

5.1 **Requirements**

a) A manufacturer, an importer or a distributor of a hand sanitiser must ensure that the hand sanitiser complies with the requirements of NAMS/SANS 490:2020, and the type of alcohol present in the hand sanitiser shall either be Ethanol (75% v/v -85% v/v) or Isopropyl Alcohol (70% v/v – 80% v/v).
b) Each manufacturer and distributor of hand sanitisers shall register with the NSI the hand sanitiser and the manufacturing facility where the hand sanitiser is manufactured, as per Section 5.2 of this document.
c) An importer must apply to the regulator for approval to the NSI for approval to import such hand sanitisers into Namibia as per Section 5.3 of this document.
d) A manufacturer, an importer or a distributor of hand sanitisers shall ensure that the packaging label is marked in accordance with the applicable Legal Metrology legislations, and supported by a valid certificate from the Legal Metrology Authority.

5.2 **Registration of local manufactured alcohol based hand sanitizer**

a) The applicant shall complete and submit an application for Product Certification using the **Product Certification Application form_PRC-P72-FA** together with supporting documents and a non-refundable application fee of N$2,150.00.
b) Upon receipt of the application form, the CB shall review the application and supplementary information to determine completeness and readiness for certification. Following the review, the CB shall either accept or decline an application for certification. A reason for declining an application for certification shall be documented and be made clear to the client.
c) The Certification Process shall be done in line with the Alcohol-based hand sanitiser scheme documents, where the CB will conduct an inspection of the manufacturing facility using the **(Alcohol based hand sanitizer Inspection Checklist_PRC-P08-01-FC)** , and collect samples for testing and analysis.
d) Samples shall be analysed for the parameters given in **Table 2: Chemical analysis** and **Table 3: Physical and microbiological analysis** as per the Alcohol-based hand sanitiser Certification Scheme**.**
e) Upon the conclusion of the inspection, and the post-inspection activities (testing results, Certification Approval 's Committee decision), a Certificate of Conformity will be issued, valid for a period of three (3) years, subjected to annual surveillance inspections to establish continuous compliance.

f) In addition to the Certificate of Conformity, the manufacturer will be issued with the NSI Standard Mark of Conformity and may affix the mark of conformity on the packaging label of the certified hand sanitiser.

g) During the three (3) years certification cycle, in addition to the annual surveillance inspections, the CB shall collect a minimum six (6) samples using **Sample Collection Form_**PRC-ABHS-P01-FA per year at different intervals at the manufacturer premises, to confirm whether the hand sanitiser continues to comply with the requirements of **NAMS/SANS 490** and regulations.

h) The sample collection will be executed based on a sampling plan (Sample collection schedule) to be prepared by the CB with cost estimate and shall be communicated and agreed upon with each manufacturer.

i) All related costs shall be borne by the manufacturer.

j) Action to be taken in case of nonconformity are stipulated in Section 5.4 of this document.

5.3 **Approval of imported hand sanitisers**

a) The importer shall complete and submit the relevant application form for the approval to import hand sanitiser into Namibia, depending on whether a mutual recognition agreement exists between the NSI and conformity assessment body in the country of origin of a hand sanitiser.

b) Where a mutual recognition agreement exists, the NSI may accept evaluation results of the hand sanitiser from the conformity assessment body if:

- the standard used is technically equivalent to NAMS/SANS 490;
- the type of alcohol present in the hand sanitiser is either Ethanol (75% v/v -85% v/v) or Isopropyl Alcohol (70% v/v – 80% v/v); and
- the criteria used to perform a conformity assessment is equivalent to the certification scheme of the NSI.

c) Customs & Excise will assist the NSI Certification by ensuring that hand sanitisers imported to Namibia comply with the provisions of the regulations at the various ports of entry. This function shall be executed as defined in the **Guide – Clearance of consignments at point of entry**_PRC-P08-1-FH.

5.3.1 Application procedures for importing of hand sanitisers under mutual recognition agreement

a) Where a mutual recognition agreement exist, the importer shall apply to the CB for the issuance of an **Attestation of Conformity_PRC-P08-01-FE** for each and every consignment to be imported in Namibia using the **Alcohol-based hand sanitisers Import Application Form**_3 submitted with all supporting documents pertaining to the specific consignment, and pay the applicable fees.

b) The CB shall review the application using the **Alcohol-based hand sanitisers Import Application Review Checklist_PRC-P08-01-FB**, and where necessary or applicable the CB may conduct a physical verification of the consignment upon entry into Namibia using **Alcohol-based hand sanitisers Product Import Physical Verification Checklist_PRC-P08-01-FD.**

c) Attestation of Conformity shall be issued for each and every consignment valid for twenty one (21) days.

d) Each Attestation of Conformity shall be identified by the **Import Reference Number (CPIR No).**

e) On an annual basis, the CB shall collect a minimum six (6) samples using **Sample Collection Form_**PRC-ABHS-P01-FA per year at different intervals at the importers depot or storage facilities

or from the market, to confirm whether the hand sanitiser continues to comply with the requirements of **NAMS/SANS 490** and regulations.

f) The sample collection will be executed based on a sampling plan (Sample collection schedule) to be prepared by the CB with cost estimate and shall be communicated and agreed upon with each importer.

g) All related costs shall be borne by the importer.

h) Action to be taken in case of nonconformity are stipulated in Section 5.4 of this document.

5.3.2 Application procedures for importing of hand sanitisers were no mutual recognition agreement exist

d) Where no mutual recognition agreement exist, the importer shall complete and submit an application for Product Certification using the **Product Certification Application Form_PRC-P72-FA** together with supporting documents and a non-refundable application fee of N$2,150.00.

e) The certification process to be followed under 5.2 a)-d) shall apply.

f) Upon the conclusion of the inspection, and the post-inspection activities (testing results, Certification Approval's Committee decision), a**n Import License_ PRC-P08-01-FF** will be issued to the importer.

g) The Import Licence is valid for a period of one (1) year, subjected to yearly renewal.

h) The importer may use the Import Licence to import and distribute hand sanitisers in Namibia.

i) During the one (1) year period, the CB shall collect a minimum six (6) samples using **Sample Collection Form_**PRC-ABHS-P01-FA per year at different intervals at the importers depot or storage facilities or from the market, to confirm whether the hand sanitiser continues to comply with the requirements of **NAMS/SANS 490** and regulations.

j) The sample collection will be executed based on a sampling plan (Sample collection schedule) to be prepared by the CB with cost estimate and shall be communicated and agreed upon with each importer.

k) All related costs shall be borne by the importer.

l) Action to be taken in case of nonconformity are stipulated in Section 5.4 of this document.

5.4 Actions to be 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.

6. Reference Documents

6.1 Product Certification Process Flow Diagram_MSC-P11-AA
6.2 Alcohol based hand sanitizer Certification Scheme_PRC-P08
6.3 Government Notice N.114 Alcohol-based hand sanitisers regulations
6.4 Certification Fees Schedule_MSC-P02-AA
6.5 NAMS/SANS 490:2020 Disinfectant Alcohol-based handrub
6.6 ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services.
6.7 ISO/IEC 17067 Conformity assessment – Fundamentals of products certification and guidelines for product certification schemes.

7. Records

7.1 Product Certification Application Form_PRC-P72-FA
7.2 Inspection Appointment Form_PRC-P72-FB
7.3 Application Review Checklist_PRC-P73-FA
7.4 Inspection Duration Determination_PRC-P73-FB
7.5 Inspection Plan_PRC-P74-FA
7.6 Sample Collection Form_PRC-ABHS-P01-FA
7.7 Alcohol-based hand sanitisers Product Import Application Form_PRC-P08-01-FA
7.8 Alcohol-based hand sanitisers Product Import Application Review Checklist_PRC-P08-01-FB
7.9 Alcohol based hand sanitizer Product Import Physical Verification Checklist_PRC-P08-01-FD
7.10 Attestation of Conformity_PRC-P08-01-FE
7.11 Alcohol based hand sanitizer Import License_PRC-P08-01-FF
7.12 Register of Alcohol-based hand sanitisers Importers_PRC-P08-01-FG
7.13 Alcohol-based hand sanitizer Plant Inspection Checklist_PRC-P08-01-FC
7.14 Certificate of Conformity_ PRC-P76_FF
7.15 Client Certification Agreement _PRC-P41
7.16 Product certification Quotation_PRC-P43-FA

8. Records of revision

Revision	Date	Description
01	May 2020	Established
02	June 2020	Added the following elements: a) 5.3 (c) The function of Customs and Excise with the clearance of consignment at point of entry