World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)

Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Vinmos Company Limited
Applicant/ Corporate address of manufacturer	Vestergaard Sarl. Place Saint François 1 1003 Lausanne, Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	Vinmos Company Limited 1 Nhan Hoa, Đuc Hoa Thuong, Long An, Viet Nam
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	31 March – 2 April 2025
Type of inspection	Re-Inspection The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements continue to be met.
Introduction	
Brief description of the manufacturing activities	Vinmos Company Limited is a contract manufacturer for Vestergaard Sarl. The production and quality control activities related to the manufacture of PermaNet 2.0, PermaNet 3.0 and PermaNet Dual were inspected.
General information about the company and site	The manufacturer held the following ISO certificates: **ISO 9001: 2015** Certified activities: Manufacture of Long-Lasting Insecticidal Nets (LLINs). Certificate number: VN17/00195 Valid from: 12 July 2023 Valid until: 12 July 2026 The certificate was issued by SGS United Kingdom Ltd.

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	ISO 14001:2015 Certified activities: Manufacture of Long-Lasting Insecticidal Nets (LLINs). Certificate number: VN23/00000337 Valid from: 12 July 2023 Valid until: 12 July 2026 The certificate was issued by SGS United Kingdom Ltd. **ISO 45001:2018** Certified activities: Manufacture of Long-Lasting Insecticidal Nets (LLINs). Certificate number: OHS 792123 Valid from: 15 August 2023 Valid until: 14 August 2026 The certificate was issued by BSI.
History	The site was last inspected by WHO in November 2018.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review including but not limited to:** • Quality Manual • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Complaints • Non-conforming products • Product release • Batch processing records • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material and finished goods • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	None
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the	• PermaNet 2.0 (Deltamethrin 55 mg/m^2) - 005-001

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inspection	• PermaNet 3.0 (roof panel: Deltamethrin 4.0 g/kg, Piperonyl butoxide (PBO) 25.0 g/kg; side panel: Deltamethrin 84 mg/m^2) - 005-002 • PermaNet Dual (Deltamethrin 2.1 g/kg, Chlorfenapyr 5.0 g/kg) - P-03228
Abbreviations	**Meaning**
CoA	Certificate of analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System
RPN	Risk Priority Number

Part 2	**Summary of the findings and comments**

1. Management Review

Management reviews were held every year, with regular communication between the two companies. The minutes of the recent management reviews were reviewed. The management review procedure titled Leadership Consideration described how to initiate a management review meeting.

The management review meeting's input and outputs were available in the minutes. Information on performance and effectiveness of the quality management system was available.

2. Leadership, responsibilities, and authorities

The quality policy had been endorsed and approved by top management, who were committed to ensuring that an effective quality management system was implemented through internal audits and management reviews.

An organizational chart was in place. The manufacturer continued to have a documented organizational structure and defined designated responsibilities and authorities for staff undertaking or verifying work affecting quality. Reporting lines for quality and production were independent of each other. The job description of the Laboratory lead and Head of quality management were reviewed.

3. Quality policy and Quality objectives

The manufacturer had an integrated policy and objectives in place. Targets had been set for each objective. The extent to which the objectives were achieved was monitored. The policy and objectives were displayed in various areas throughout the facility.

4. Document control

The manufacturer had a procedure available for the control of documents. There were 4 tiers of document hierarchy. A distribution register was in place. Obsolete documents were to be retained for 3 years before destruction. The destruction record was reviewed. Documents were available at the point of use and were available in the local language.

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5. Personnel competence and training

The procedure for the training process was reviewed. The procedure was applied to professional training activities, including internal and external training. The Human Resource department was responsible for collecting information on identified training needs, evaluating human resources, developing a training program (internal training) for new employees, and creating a yearly training plan. The department heads were responsible for evaluating employee competencies and planning human resources for their department.

Training evaluation records were retained for 5 years. The training and assessment plan for 2025 was checked. The training evaluation records on were reviewed.

6. Risk Management

The manufacturer had a documented process for evaluating risk throughout the full life cycle of the product.

The following documents were reviewed:

- Risk identification and Control procedure
- Risk Assessment guidelines
- Risk assessment register
- Summary table of Hazard levels, cause analysis, and Prevention/improvement plan
- Accident Risk Identification and assessment matrix – Occupational Health

A flow chart for conducting a risk assessment was available. The criteria for the calculation of the level of risk were defined. The manufacturer had a committee that was responsible for reviewing identified risks. The frequency for review of risks was defined.

7. Internal Audits

The procedure for internal audits was reviewed. The procedure applied to the quality management system, environmental management system, social responsibility system, and occupational safety and health management system. The director was responsible for approving the internal audit plan. The ISO board was responsible for developing the internal audit plan and program. Internal audits were conducted by an assessment team (Internal audit team). Any identified nonconformities were documented on the assessment record sheet and signed by the representative of the department being audited. The ISO committee was responsible for summarizing the nonconformities into the internal assessment summary report. The identified nonconformities were handled following the procedure for nonconformities. The internal audit program for 2025 was in place. The list of internal auditors was also in place. It was demonstrated that the internal auditors were not auditing their own areas of work.

8. Control of nonconforming products

The procedure for nonconformity control and corrective actions was reviewed. The procedure applied to all personnel involved in processes of controlling nonconformities, implementing corrections and corrective actions of the quality management system, environmental management system, occupational safety and health management system, and social responsibility system. All officers and employees were responsible for reporting nonconformities to the head of the unit or the ISO department. Nonconformities were recorded on the Nonconformity report and corrective action

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request form. The department in which the Nonconformity was identified was responsible for determining the root cause of the nonconformity and recording it in the Nonconformity report and corrective action request form. Based on the identified root cause, the head of the unit was responsible for proposing corrective actions and the expected completion time. The ISO committee chair was responsible for reviewing the proposed corrections and corrective actions. The Nonconformities were categorized into major and minor.

9. Control of Changes

Changes at the facility were managed using the Vestergaard procedure for change management in the production of Vestergaard vector control products. The purpose of the procedure was to effectively manage all changes applying to the manufacturing of Vestergaard vector control products including raw materials, product specifications, control plans, process specifications, machinery, supply agreement and technical documentation etc. Changes were categorized as major or minor. The procedure also listed the notifiable changes to WHO. Changes were requested using a change order form. The changes were registered in the master list. Changes were reviewed, and the impact of the change was assessed by the Change Order Review Group. Selected changes were reviewed.

10. Complaint Handling

The procedure for handling customer complaints and product recalls was reviewed. All complaints were received by the Vestergaard headquarters in Lausanne, Switzerland. Complaints were registered in the customer complaint record file and assessed to determine the level of investigation required. Selected complaints were reviewed.

11. Design and development of products

This site was not involved in design and development of products under the scope of the inspection. This area was therefore not inspected.

12. Support

Infrastructure and work environment

The infrastructure at the site was well maintained and clean. All staff observed were wearing appropriate PPE. Rodent traps were in place and daily checks of traps were available.

Monitoring and measuring resources

The manufacturer had a procedure for the management of equipment. The procedure adequately described how to calibrate the equipment with pictorials available. The head of each department were responsible for the equipment maintenance schedule for their area. Maintenance schedules were in place and maintenance reports were available. External calibration reports were verified and approved before the equipment released for use. Calibration records of selected equipment were reviewed.

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13. Production and service provisions

Control of Production

The manufacture of PermaNet Dual involved pre-mixing, milling, post-mixing, chemical mixing, impregnation, cutting, sewing, labelling, packaging, and baling. Selected batch records were reviewed. The in-process parameters monitored including active ingredient content in the water dispersible preparations, mixing time, mixing speed, and product temperature.

The product quality attributes monitored included weight (GSM), mesh size, width, and bursting strength. The temperatures of the different zones of the stenter were monitored. The heat setting monitoring sheet was in place. The procedure for cleaning was reviewed. Cleaning records were in place. Milling line 2 was equipped with an inline cleaning program. Batch numbering instructions for PermaNet 2.0, PermaNet 3.0 and PermaNet Dual were available. Label issuance and control were verified.

Qualification and validation

The installation qualification reports for the milling lines were in place. The reports defined the milling specifications and parameters. The ranges of the different parameters monitored during the installation qualification were provided.

The operational qualification (OQ) report was also reviewed. The OQ parameters were defined. The results for the product quality attributes verified were available.

The process validation protocols for both Chlorfenapyr water dispersion and Deltamethrin water dispersion were also reviewed.

Quality Control Laboratory

The Quality Control Laboratory was well maintained and clean with appropriate equipment that was fit for purpose. The laboratory was temperature controlled and monitored. Standards used in the QC laboratory were stored within a monitored refrigerator.

The procedure for the determination of active ingredient content in polyester PermaNet Dual using HPLC chromatogram was reviewed. Test reports and raw data of selected batches were verified. The analytical method validation reports for the determination of Deltamethrin and Chlorfenapyr contents in PermaNet Dual, the analytical method validation report for the determination of Deltamethrin content in milling samples using HPLC and the procedure for the determination of particle size using the distribution analyzer were also reviewed.

Control of Waste

Waste generated from production activities was collected in a central location. The waste was then collected by a third-party company for treatment.

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14. Preservation

The procedure for the incoming chemical inspection record was reviewed. The procedure described the handling of materials at receipt and documents to be provided at receipt of raw materials. The manufacturer verified the quantities and physical appearance of the containers of the raw materials received. There were designated warehouse areas for storage of chemicals and fabric. The manufacturer had in place a chemical compatibility chart. Material safety data sheets were also in place. Inventory records were in place. The warehouse was equipped with spill containment pallets, spill kits, fire extinguishers and water sprinklers.

15. Retention samples

An area for the storage of retention samples was available. The temperature of the storage area was monitored. An inventory of material was available. Retention samples were kept for 4 years.

16. Control of externally provided processes, products, and services

Vestergaard was responsible for the selection and evaluation of suppliers. Overall, the review process for suppliers was comprehensive and detailed. An annual review was performed with regular on-site audits being performed when required.

Part 3	Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken and planned by **Vinmos Company Limited** located at **1 Nhan Hoa, Đuc Hoa Thuong, Long An, Viet Nam** was considered to be operating at an acceptable level of compliance with the ISO 9001: 2015 Standard.

All the non-conformances observed during the inspection that were listed in the full report, as well as those reflected in the WHOPIR, were addressed by the manufacturer to a satisfactory level prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of Standards and Guidelines referenced in the inspection report

1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5th edition (2015), ISO/FDIS 9001: 2015 ***Short name: ISO 9001:2015***
   https://www.iso.org

2. Manual on the Development and Use of FAO and WHO Specifications for Pesticides, First edition -third revision. Pesticide specifications. FAO plant production and protection paper (228), FAO/WHO Joint Meeting on Pesticide Specifications (JMPS), Rome 2016
   http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/manual/en/

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