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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
Corporate address of manufacturer	1 Nhon Hoa hamlet, Duc Hoa Thuaong commune, Duc Hoa district, Long An province, Vietnam.
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	As above.
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	19-20 November 2018
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard
Introduction	
Brief summary of the manufacturing activities	Vinmos Company Limited, 1 Nhon Hoa hamlet, Duc Hoa Thuaong commune, Duc Hoa district, Long An province, Vietnam: Vinmos Company Limited is a contract manufacturer for Vestergaard S.A. Activities carried out at this site included warehousing of untreated fabric and finished goods (bed nets), processing of the fabric (coating), cutting, sewing, stitching, labelling, baling, packaging and quality control testing of Long Lasting Insecticide treated Nets (LLIN). Both in-process physical and chemical quality control tests were performed at this site. Final physico-chemical release tests were performed at Vestergaard Vector Control Laboratory located at 9/253 Minh Khai street, Hai Ba Trung district, 114034 Hanoi, Vietnam.
General information about the company and site	ISO 9001:2015 certification: Date of issue 20th July 2017, Expiry date 20th July 2020, Certificate number VN17/00195. Issued by SGS. Scope: Manufacture of Long Lasting Insecticidal Nets (LLINs).
History	This was the first WHO audit of the site

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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 • Data integrity • Product release • Batch processing records • Laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Quality control laboratory • Raw material and finished goods • Production areas
Exclusions and Non-applications of requirements in the QMS	Design and development were excluded from applications of the ISO 9001: 2015 standard.
Out of scope	Products not submitted to WHO for prequalification
Restrictions	None
WHO products covered by the inspection	PermaNet® 2.0 (*Deltamethrin* 55 mg/m^2) 005-001
Abbreviations	**Meaning**
LLIN	Long-lasting insecticide nets
MSDS	Material safety data sheet
PPE	Personal Protective Equipment
QA	Quality assurance
QMS	Quality management system

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Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

The organizational roles and responsibilities were described and communicated within the organization. The organogram showed that the reporting lines of the Quality Control were independent of those for production management.

2. Quality policy and quality objectives

The quality policy and objectives were documented and were considered adequate to the purpose and context of the organization and met the requirements of the standard. The policy is communicated to the workforce and is displayed throughout the facility in English and the local language.

3. Management review

An established procedure for management review was in place. Management reviews were conducted once a year. Management review was performed in accordance with the established procedure and met the requirements of the standard. The minutes of the last meeting held on 26th June 2018 were reviewed. Management reviews were conducted in accordance with the procedure. These were found satisfactory.

4. Leadership

From the information described and reviewed; top management was committed to the effective implementation of the QMS. Resources necessary for implementation of the QMS were determined and provided. The manufacturer monitored and measured the ability of the quality management system to meet planned results. Top management engaged, directed and supported personnel in fulfilling their responsibilities and roles.

5. Control of documented information

The established procedure for documented information was in place. Control of documented information was managed centrally by Vinmos Company Limited. Document control was described in the quality manual. It adequately described creation, approval, distribution and review documents. Records were retained for 5 years.

6. Personnel competence and training The relevant procedure for training was in place. Training plans were generated on a quarterly basis. The procedure provided for ad hoc trainings. Training plan for 2018 was reviewed. Training records for the personnel involved with some of the critical the manufacturing steps, for example 'impregnation and heat setting' were reviewed. Effectiveness of trainings was evaluated.

7. Risks and opportunities

The procedure for risks assessment was reviewed. The procedure described the methodology for risk identification, analysis, evaluation. A risk register was available. The risk impact, probability and rating/score were indicated along with the mitigations. The risks pertaining to the heat setting workshop were reviewed in detail. Risks were reviewed annually. Risks are routinely reviewed as part of the management review meeting and were included in the meeting agenda.

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8. Control of changes

The facility had an established procedure for change control. Changes to processes were forwarded to Vestergaard for review and approval. The facility maintained a change control register. Change were reviewed and found satisfactory.

9. Internal Audits

Internal audits were conducted in accordance with a relevant established procedure. The audits are conducted annually. The internal audit plan schedule for 2018 was available. ISO 9001 was used as the criteria for internal audits. Internal audit report for 2018 and corrective actions were reviewed and found satisfactory.

10. Control of non-conforming products

The manufacturer had a number of measures in place for quality control and detection of nonconforming goods including, physical inspection of knitted fabric and sewn bed nets in accordance with the established procedure for control of non-conformances and corrective action. Records on defects identified were maintained. A procedure for handling of non-conforming results in the laboratory was also in place. It allowed for investigations both in laboratory and production, resampling and retesting.

11. Performance evaluation

The manufacturer monitored key processes and product quality parameters such as mesh size, weight, bursting strength, *Deltamethrin* content etc. The Acceptance, Testing and Inspection (ATI) records for the month of January to October 2018 were reviewed. The results were analyzed. The records reviewed showed that processes were within control limits.

12. Complaint handling and Customer satisfaction

Complaints were handled by Vestergaard. The complaint handling process involved root cause analysis, corrective action and follow up on the implementation of the corrective action. At the time of the audit, no complaints related to the manufacturing of LLINs at the site had ever been received by Vestergaard.

13. Design and development of products

Design and development were excluded from applications and requirements of the ISO 9001: 2015 standard.

14. Support

Infrastructure and work environment

The infrastructure at the site was generally well maintained. The floors and external environments were clean and adequately maintained. MSDSs were available in the warehouses. The staff were provided with PPE.

Monitoring and measuring resources

The calibration and maintenance plan for 2018 was in place. The equipment qualification, calibration and maintenance records were available. Calibration records for balances and maintenance records for stenters and sewing machines were reviewed and found satisfactory.

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15. Production and service provisions

Control of Production

At the time of the inspection facility only PermaNet® 2.0 was manufactured at the site. The manufacture of PermaNet® 2.0 involved chemical treatment stentering, cutting, sewing, stitching, labelling, packaging and baling. The water used in production was treated using reverse osmosis purification technology. The pH of the water was monitored online. The bed nets were impregnated and dried. Processing temperatures were controlled, monitored and recorded. In-process parameters were monitored. The temperature indicators were calibrated.

The dimensions of the fabric to be cut were determined using calibrated tape measures. Production records were reviewed. Traceability of the batch numbers to the active ingredients, laboratory results etc. was possible. Finished bed nets were sampled and sent to Vestergaard Vector Control Laboratory. The finished bed nets were released following analysis and review of production data by the Quality Assurance Executive of Vestergaard.

The laboratory carried out physico-chemical in-process test on the bed nets. These included bursting strength, GSM, *Deltamethrin* content, denier among others A sample register was in place. Samples were adequately labelled and stored. The equipment in the laboratory was calibrated. Laboratory test results were adequately documented. The *Deltamethrin* content test reports for PermaNet® 2.0 were reviewed and found satisfactory. All the issues raised related to control of production were addressed satisfactorily by the manufacturer.

Identification and traceability

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability.

Release of products and services

Samples of the bed nets (finished product) were sent to Vestergaard Vector Control Laboratory at 9/253 Minh Khai street, Hai Ba Trung district, 114034 Hanoi, Vietnam for analysis. Batch release followed review of production data and laboratory test results from Vestergaard Vector Control Laboratory. Analytical results from the Vestergaard Vector Control Laboratory were used for release of bed nets to the market. Batch release was done by the Quality Assurance Executive of Vestergaard.

16. Preservation

The temperatures in both the chemical raw material and finished product warehouses were ambient. Records of the inventory were maintained. The containers of the raw materials were inspected for damages and quantities confirmed upon receipt. The manufacturer relied on Certificates of Analysis provided by supplier. Stock card were available.

17. Post-delivery Activities

Storage stability

One batch per order was subjected to accelerated stability studies. The batches were subjected to temperatures of 40±2ºC for 8 weeks. Results of the analysis for several batches of PermaNet® 2.0 were reviewed and found to comply with specifications. These studies were conducted by Vestergaard.

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18. Control of externally provided processes and products

Selection of suppliers was managed by Vestergaard. The procedure for control of suppliers described the criteria for selection of suppliers which involved audit of the supplier and performance review of the suppliers. The audit of the supplier was conducted using a questionnaire. Performance review of the suppliers was conducted annually. A list of critical suppliers was in place. Performance reports of critical suppliers were and found satisfactory.

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 ***Vinmos Company Limited*** located at ***1 Nhon Hoa hamlet, Duc Hoa Thuaong commune, Duc Hoa district, Long An province, Vietnam*** 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. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange" Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. 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/