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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	Shobikaa Impex Private Ltd
Corporate address of manufacturer	Shobikaa Impex Private Limited 34 Sannathi Street, Vennaimalai (PO), Karur – 639 006 Tamil Nadu, India
Inspected site	
Name & address of inspected manufacturing site(s)	Name: Shobikaa Impex Private Limited Addresses: a) SF No.558,559, Athur SIDCO Industrial Estate, Vennaimalai PO Karur, Tamil Nadu 639006 India. b) SF. No. 37/A2, Units-A, B&C, D. E Coimbatore Road, Thannerpandal, Pavithram Village, Karur – 639 002. Tamil Nadu, India c) Plot Number 32-37, Athur SIDCO Industrial Estate, Vennaimalai (PO), Karur - 639006, Tami Nadu, India d) SF No.694/4, Pavithiram Village, Chinnatharapuram Road, Karur, Tamil Nadu, 639 002. e) (Semmadai), SF No.499/1, Athur Village, Manmangalam (TK), Vennaimalai (PO), Tamil Nadu, Karur, 639 006, India f) SF No 419/2, 421/1, 423 Athur Sidco Industrial Estate Vennaimalai (PO), Karur 639006 Tamil Nadu, India
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	14 -16 November 2022
Type of inspection	Re-inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	Shobikaa Impex Private Ltd commenced the manufacture of mosquito net fabric for the domestic market in 2000. In 2015 the facility started the manufacture of LLINs.

a) Shobikaa Impex Private Limited: SF No.558,559, Athur SIDCO Industrial Estate, Vennaimalai PO Karur, Tamil Nadu 639006 India

The activities at this site included warehousing, production of master batch, extrusion, knitting, cutting, sewing, labelling, baling, packaging. Quality control testing (both physical and chemical testing) of Long-Lasting Insecticide treated nets (LLIN) was performed at this site.

b) Shobikaa Impex Private Limited: SF. No. 37/A2, Units-A, B&C, D. E Coimbatore Road, Thannerpandal, Pavithram Village, Karur – 639 002. Tamil Nadu, India

The fabric was received from site (a) above – located at SF No.558,559 Vennaimalai for further processing. The activities at this site included cutting, sewing, labelling, baling.

c) Shobikaa Impex Private Limited: Plot Number 32-37, Athur SIDCO Industrial Estate, Vennaimalai (PO), Karur - 639006, Tami Nadu, India

The activities performed at this site included mixing and extrusion.

d) Shobikaa Impex Private Limited: SF No.694/4, Pavithiram Village, Chinnatharapuram Road, Karur, Tamil Nadu, 639 002.

The activity at this site was only warehousing of the packaged bed nets.

e) Shobikaa Impex Private Limited: (Semmadai), SF No.499/1, Athur Village, Manmangalam (TK), Vennaimalai (PO), Tamil Nadu, Karur, 639 006

The activity at this site was only warehousing of the packaged bed nets.

f) Shobikaa Impex Private Limited: SF No 419/2, 421/1, 423 Athur Sidco Industrial Estate Vennaimalai (PO), Karur 639006 Tamil Nadu, India

The inspection activities performed at the time of the inspection included the recycling of the PET bottles to produce yarn. The other planned activities following the manufacture of the yarn from PET bottles included knitting, coating, cutting, sewing,

	labelling, and packaging. At the time of the inspection installation of some of the equipment for the coating process was still ongoing.
General information about the company and site	The site held the following ISO certificates. • ISO 9001:2015 certificate - 99 100 16065. Valid from 21/3/2022 to 07/01/2024. Scope: Management, marketing, purchase, and human resources for manufacture and export of Long Lasting Insecticide incorporated nets. • ISO 45001:2018 certificate – 99 117 00350. Valid from 21/3/2022 to 16/11/2023. Scope: Management, marketing, purchase, and human resources for manufacture and export of Long Lasting Insecticide incorporated nets. • ISO 14001:2015 certificate – 99 104 00681. Valid from 21/3/2022 to 16/11/2023. Scope: Management, marketing, purchase, and human resources for manufacture and export of Long Lasting Insecticide incorporated The certificates were issued to TUV SUD.
History	The facility was last inspected by WHO in February 2019. All the raised nonconformances from the previous inspection were verified. The corrections and corrective actions in place were found adequate and satisfactory. There were several major changes since the last inspection, and these included: • Construction and operationalization of PET recycling facility • Discontinuation of DuraActive LLIN • Two new warehouses used for storage and distribution of finished bed nets as indicated in section 5 above • Addition of another manufacturing site located at Plot Number 32-37, Athur SIDCO Industrial Estate, Vennaimalai (PO), Karur - 639006, Tami Nadu, India

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	Design and development of products and services (Clause 8.3) was also excluded from the requirements of the QMS.
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection. DuraActive LLIN was discontinued and was therefore not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• 006-001 DuraNet LLIN (Alphacypermethrin 5.8g/Kg) • 006-003 DuraNet Plus (Alphacypermethrin 6.0g/Kg, Piperonylbutoxide (2.2g/Kg) • 006-004 DuraNet Plus 2.0 (Alphacypermethrin - 5.8g/Kg, Piperonylbutoxide -10g/Kg) • P-00320 Green Net (Deltamethrin 1.4 g/kg)
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System
PBO	Piperonylbutoxide
RPN	Risk Priority Number

Part 2	Brief summary of the findings and comments

1. Quality policy and quality objectives

An established quality policy was in place. The quality policy was signed by the Managing director and included the following commitments:

- Complying with applicable legal and other requirements
- Continually improving the performance of IMS through monitoring and review.

The quality objectives were defined in the Integrated Management System (IMS) manual. The quality objectives process performance, customer satisfaction, environmental management system, occupational health and safety among others had been defined and established. The quality objectives were monitored and measured. The results of the monitoring and measurement of the quality objectives was discussed in management review. The quality policy and quality objectives were communicated through trainings and were displayed at various locations throughout the facility.

2. Management review

Management reviews were held every six months. The minutes of the latest management review were reviewed. The following were agenda items discussed in the management review meeting: management review updates, Changes in the external and internal issues, internal audits, customer satisfaction surveys and trends, customer complaints, feedback from relevant interested parties, process performance and product conformity, status of corrective and preventive actions, follow-up of previous management review minutes, suitability of IMS policy and objectives, resources requirements, performance of ongoing IMS objectives and review of management programs, compliance to legal and other requirements, recommendations for improvement etc. These were found satisfactory.

3. Leadership

An organogram was in place. The site was headed by the Managing Director. The General Manager (Operations, Extrusion and Knitting) and General Manager – Sewing reported to the CEO. The Quality Assurance Manager also reported independently to the CEO. The CEO reported to the Managing Director. Top management demonstrated commitment to the implementation of the QMS by promoting improvement and taking accountability of the effectiveness of the quality management system. These were achieved through trainings, internal audits, implementation of corrections and corrective actions, performance evaluations, management reviews etc.

4. Control of documented information

The relevant procedure for document control was reviewed. The procedure outlined the steps for creation and updating documents. Documents were categorized into 6 tiers i.e. Level 1 – IMS Manual, Level II A – IMS SOPs, Level II B - IMS Process Models, Level III - IMS technical and allied Doc, Level IV - IMS work Instructions and Level V - IMS forms and formats. External documents were identified and controlled. A master list of external documents was in place. The external documents included ISO standards, ISO testing standards, WHO CIPAC standards etc. Documents were available in both hard and softcopies. Access to the soft copies of the SOPs was controlled with passwords and were under custody of the QA manager. A list of documents indicating the retention periods and disposing authority was in place.

5. Personnel competence and training

The training procedure was reviewed. The annual training plan for the period January – December 2022 was reviewed. The planned trainings included induction training, training of software, on-job training, awareness – policy and objectives, safety training and special development training among others. Training records which included the training log and training evaluation form were in place. An annual performance evaluation on the execution of the training plan was also conducted. The training log provided information on the topic of the training to be conducted, the names of the trainer and trainees. Training records of were reviewed and found satisfactory.

6. Risks Management

The procedure for risk management was discussed. The procedure described risk identification, analysis, and evaluation. The risk evaluation criteria included probability and severity of the risk. Risk were categorized into 3 classes i.e. I, II and III. A risk and opportunity matrix was defined in the IMS manual.

7. Control of changes

The procedure for change control was reviewed. Changes were categorized into Critical, Major and Minor. Changes were requested using change request form. Changes were reviewed and found satisfactory.

8. Internal Audits

The procedure for internal audits was reviewed. The procedure emphasized the need to avoid conflict of interest when selecting auditors. The criteria of the internal audits was ISO 9001:2015, 14001 :2015 and 45001:2018 standards. The audit plan was in place. Internal audit records were reviewed. The internal audit circular was signed by the Management Representative. Some of the areas audited included top management on the provision of resources, infrastructure and management reviews monitoring and measurement of processes and the handling of complaints etc. The effectiveness of the implemented corrections and correctives actions was reviewed and verified prior to closure of the nonconformities. Training records of internal auditors were also reviewed.

9. Control of nonconforming products

The relevant procedure for control of non-conformities was reviewed. Nonconformities related to raw materials were handled by the supply chain manager and the ones related to mixing, extrusion, sewing, knitting etc. were handled by the General Managers in charge of production activities. The manufacturer had a documented criteria for assessment of bed net defects such as holes, stains, tears etc. The defects were classified as Critical, Major and Minor. Repairable defects such as holes were repaired by stitching. The repaired bed nets were re-inspected to ensure that they conform to the specified requirements. All nonconformities were documented.

10. Performance evaluation

The process performance at each of the sites involved the extrusion, cutting, sewing, and packaging activities was measured and monitored. Some of the parameters monitored included chemical plant mixture temperature, chemical plant extruder temperature, stenter chamber temperature and yarn thickness. Other parameters monitored included complaints, customer satisfaction. Performance evaluation showed that the processes were satisfactory. The performance evaluation was performed using graphs.

11. Design and development of products

Not applicable. The site was not involved in design and development activities.

12. Customer satisfaction

The manufacturers received feedback on their products from customers through surveys. A customer survey to IDA foundation following the supply of DuraNet and DuraNet Plus LLIN was reviewed. The survey collected information on the quality included packaging, and overall performance of the services and products. IDA foundation was satisfied with the products as met their expectations.

13. Complaints

The procedure for handling complaints was reviewed. Complaints were received by the Manager logistics and together with a team comprised of members from other departments such as QA, QC, Production complaints were investigated, corrections and corrective actions implemented. A customer feedback form on which the complainant documented the complaints was in place. A complaint investigation form was also in place. The information documented on the complaint investigation form included name of the customer, complaint reference number, nature of the compliant, analysis of complaint, corrective action. No complaints had been registered for the period January - November 2022.

14. Support

Infrastructure and work environment

The site was well maintained. The laboratory and production areas were equipped with safety equipment such as fire extinguisher, eye shower and fume hood. The personnel were provided with personal protective equipment such as gloves, boots, googles etc.

Monitoring and measuring resources

An equipment maintenance schedule was in place. The maintenance records for the extruder were in place. Some of the extruder parameters/ parts maintained included gearbox, barrel, valves, cutter, performance etc. The balance number used for dispensing of the raw materials was calibrated. Calibration records were available. The calibration records for the standard weights were also available.

15. Production and service provisions

Control of Production

The manufacturer had only produced commercial batches of DuraNet LLIN and DuraNet Plus. No commercial batches of DuraNet Plus 2.0 and Green Net had been manufactured at the time of the inspection.

Shobikaa Impex Private Limited: SF No.558,559, Athur SIDCO Industrial Estate, Vennaimalai PO Karur, Tamil Nadu 639006 India

Inventory records in the warehouse were managed by use of stock cards and a customized ERP. Data on the raw materials, batch number, quantities of raw materials received, quantities of the raw materials issued was maintained in the ERP software. The procedure for receipt of the raw materials, packaging materials and accessories was reviewed. The sampling plans were described. Raw materials were received along with the certificate of analysis. The quantity, label information, physical conditions of the containers, vendor were also verified on receipt of the raw materials.

Raw materials were staged in the dispensing area. Dispensing records were maintained. The dispensing records allowed for traceability of the of the batch number and quantities of the raw materials dispensed.

The manufacture of Alphacypermethrin master batch (DuraNet Plus) involved the mixing of Alphacypermethrin technical material with other ingredients, extrusion, cooling, pelletizing, and packaging. The temperatures of the different extrusion zones and the water bath were monitored, and records maintained. The manufacture of the master batch for (DuraNet LLIN) was similar to that that of DuraNet Plus except that there was not addition of PBO to the mixture. Every batch of the master batch was sampled and tested for Active ingredient content.

An automatic dosing system controlled the quantities of the raw materials mixed. This was the followed by extrusion, warping, knitting, cutting, sewing, and packaging. The in-process parameters included the monitored in-process parameters included, bursting strength, GSM, and yarn thickness. The extrusion temperatures were monitored, and records maintained. At the time of the inspection manufacture of DuraNet LLIN was ongoing. Cleaning records of the Knitting machine were in place. All the sewed bed nets (100%) were inspected for defects such as hole, stains, open seams etc. Inspection records were maintained. Labels issuance and reconciliation records were in place. All labels are verified and approved by QA before they are printed and released. The sewed nets were then packaged and labelled. The batch production records for DuraNet were reviewed. Products were released by QA Manager following review of both production and laboratory data.

Shobikaa Impex Private Limited: SF. No. 37/A2, Units-A, B&C, D. E Coimbatore Road, Thannerpandal, Pavithram Village, Karur – 639 002. Tamil Nadu, India

The impregnated fabric was received from the above site – located at SF No.558,559 Vennaimalai for further processing. The received fabric was inspected for defects, cut, sewed, labelled, and packaged according to customer specifications. The measuring tapes were identified and calibrated. All the sewed bed nets were inspected for defects. The daily net inspection procedure and daily inspection report were reviewed. The packaged finished bed nets were transported to the warehouses for storage and distribution.

Shobikaa Impex Private Limited: Plot Number 32-37, Athur SIDCO Industrial Estate, Vennaimalai (PO), Karur - 639006, Tami Nadu, India

The master batch was received from the site located at SF No.558,559 Vennaimalai. The Master was appropriately stored. The activities at this site included mixing of the master batch mixed with other ingredients, extrusion. The quantities, batch numbers of the master batch received, and production output were recorded in the ‘‘Daily Chemical Taken record’’ and Production record respectively. The temperatures of the water bath and extruder were monitored and recorded. The filaments were then warped onto the beams and transported to SF No.558,559 Vennaimalai for knitting.

Shobikaa Impex Private Limited: SF No.694/4, Pavithiram Village, Chinnatharapuram Road, Karur, Tamil Nadu, 639 002 and Semmadai), SF No.499/1, Athur Village, Manmangalam (TK), Vennaimalai (PO), Tamil Nadu, Karur, 639 006

The finished bed nets from the other sites were stored at this site. The bed nets were delivered along with a delivery slip that had details of date of delivery, source of the bed nets, truck number, batch number, color, quantity etc. An inward receipt register was also in place. The inward receipt register contained information on quantity received, quantity out, closing balance, batch number, size, color etc.

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Empty plastic bottles were collected from various part of the country and transported to the site for recycling. The bottles are then washed and sorted. The bottles were washed with hot water, cut into smaller pieces, shifted, washed again and dried. This was then followed by mixing the cut plastic bottles with other ingredients. The extrusion temperatures were monitored. The whole process was monitored and controlled using a customized software. Access to the control panel was controlled by use of unique passwords.

At the time of the inspection installation of some several equipment for the coating process was still ongoing. It was discussed with the manufacturer to consider equipment performing equipment qualification and process validation. It was further discussed that this documentation be retained. The other activities planned that would follow the manufacture of yarn were knitting, coating, cutting, sewing, labelling, and packaging.

The quality control laboratory performed both physical and chemical tests of both in-process and finished product samples. A sample register was in place. The standard testing procedure and test reports for determination of Alphacypermethrin (Duranet LLIN) were reviewed.

Waste generated during production was collected and treated by a third party company – Green Gene Enviro Protection and Infrastructure Private Ltd.

16. Post-delivery Activities

Samples were stored in a dedicated area. The samples were adequately labelled. A retention sample register was in place. A sample of each batch was retained. The samples were stored at ambient temperatures. The samples were retained for a period equivalent to the shelf life of the product plus one year.

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

The relevant procedure - Supply chain/Stores was reviewed. The procedure described the criteria for selection and evaluation of suppliers. The criteria for evaluation of suppliers was defined. Assessment reports for the suppliers of PBO and Alphacypermethrin technical material were reviewed 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 ***Shobikaa Impex Private Limited*** located at:

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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/