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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 & addresses of inspected manufacturing site(s)	Shobikaa Impex Private Limited a) SF No.419 - 430 Athur SIDCO Industrial Estate, Vennaimalai City: Karur State/Province: Tamil Nadu Zip code: 639006 Country: India. b) No.32-37, Athur SIDCO Industrial Estate, Vennaimalai Post City: Karur State/Province: Tamil Nadu Zip code: 639006 Country: India
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	12-16 August 2024
Type of inspection	Initial inspection The inspection was to establish that the applicable requirements of ISO 9001:2015 as well as WHO specific requirements were met.
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 2005 the facility started the manufacture of LLINs. Shobikaa Impex Private Ltd manufactured Interceptor G2 (LLINs) on contract for BASF.
General information about the company and site	The site held the following ISO certificates. • ISO 9001:2015 certificate – Number 99 100 16065. Valid from 08/01/2024 to 07/01/2027. Scope: ‘‘Management, Marketing, Purchase and Human Resources for Manufacture and Export of Long-Lasting Insecticide Incorporated/Coated Bed Nets and Manufacture of 100% Recycled Polyester Multifilament yarns such as Partially Oriented Yarn, Fully

	Drawn Yarn & Draw Texturized Yarn from Post Consumer PET bottles''. • ISO 14001:2015 certificate –Number 99 104 00681. Valid from 17/11/2023 to 16/11/2026 Scope: ''Management, Marketing, Purchase and Human Resources for Manufacture and Export of Long-Lasting Insecticide Incorporated / Coated Bed Nets and Manufacture of 100% Recycled Polyester Multi filament yarns such as Partially Oriented Yarn, Fully Drawn Yarn & Draw Texturized Yarn from Post Consumer PET bottles'' • ISO 45001:2018 certificate – Number 99 117 00350. Valid from 17/11/2023 to 16/11/2026. Scope: ''Management, Marketing, Purchase and Human Resources for Manufacture and Export of Long-Lasting Insecticide Incorporated / Coated Bed Nets and Manufacture of 100% Recycled Polyester Multi filament yarns such as Partially Oriented Yarn, Fully Drawn Yarn & Draw Texturized Yarn from Post Consumer PET bottles''. The certificates were issued by TUV SUD South Asia Private Ltd, Mumbai.
History	The site was previously inspected by WHO in February 2019 and November 2022.
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 were not applicable as the site was not involved in the design and development activities.
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 inspection	• 006-001 - DuraNet LLIN (Alphacypermethrin 5.8g/Kg) • 006-003 - DuraNet Plus (Alphacypermethrin 6.0g/Kg, Piperonyl butoxide (2.2g/Kg) • P-00320 - GreenNet (Deltamethrin 1.4 g/kg) • 002-002 - Interceptor G2 (200 mg/m^2 Chlorfenapyr, 100 mg/m^2 Alpha-cypermethrin).
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. Quality policy and quality objectives

The facility had a documented and established quality policy which was appropriate for its purpose. The quality policy was displayed throughout the facility and available in both English and the local language. There had been no change to the quality policy since the last WHO inspection.

The manufacturer had documented and established quality objectives. The objectives were monitored and measured.

2. Management review

Management review meetings were carried out in accordance with an established procedure. The management meetings were held every 6 months. The structure of the meeting was found to be compliant and structured according to the ISO 9001 standard requirements.

Management review minutes for the meetings held in 2024 together with the exceptional meeting held to discuss the new product (GreenNet) were reviewed. The KPIs were reviewed.

3. Organizational roles, responsibilities, and authorities

The organization had a documented quality management manual that defined roles and responsibilities of management, including an organizational chart that showed the reporting line and interactions between different departments and functions. Reporting lines for production and quality control departments were independent of each other. Top management of the facility was committed to the development and implementation of the Quality Management System (QMS). Responsibilities and authorities for the different roles were assigned.

The quality manual adequately described the roles and responsibilities of the Management Representative. The job description of the Quality Assurance Manager was also reviewed.

4. Document control

The manufacturer's Quality Manual had been revised to include the new product GreenNet. It adequately addressed and reflected the intended practices of the manufacturer. It contained a description of the interaction between the processes of the Quality Management System (QMS) and defined the structure of the documentation system. The quality manual incorporated the following international standards:

•ISO 9001:2015 – Quality Management Systems - Requirements
•14001:2015 – Environmental Management Systems (EMS)
•45001:2018 – Occupational Health and Safety Management

The manufacturer had in place a procedure for the control of documents. Documents were maintained electronically with hard copies available at the point of use. A similar QMS was applied across all the subsidiary sites. Documents were reviewed on a three-year cycle. A change request form was provided when documents were required to be changed or reviewed. Changes were reviewed. Translation of some of the documents into local language was in progress at the time of the inspection. Translation of key documents had already been completed with other documents underway.

A distribution list was available in hard copy. The retention period for the documents and the certificate of analysis was for 4 years.

5. Risk Management

The procedure for Risk Management was reviewed. Risk assessment was conducted once every year. Risks were also assessed whenever new machines, materials and procedures were introduced. This SOP applied to the processes for the manufacture of netting fabric. The manufacturer also had in place another risk management procedure that described the evaluation and assessment of risks related to the production of PET flakes and FDY, POY and DTY yarn. The procedures also described the criteria for risk analysis.

A risk assessment register related to production of the fabric and PET flakes, yarn (POY and FDY) were reviewed.

A quality risk management register for the quality control processes, ETP (Effluent Treatment Plant), ultrafiltration and reverse osmosis, and multi effect evaporator were in place.

6. Internal Audits

The facility had an established procedure for internal audits. Internal audits were conducted every 6 months with a team of internal auditors who were independent of the area being audited and this was verified. The audit and audit checklist covered all three standards (ISO 9001, ISO 14001, and ISO 45001). The findings were classified as either major or minor.

7. Customer Satisfaction and complaints

Customer satisfaction surveys were conducted using questionnaires. At the time of inspection only two customer satisfaction surveys had been conducted. The manufacturer had received positive feedback.

At the time of the inspection, the manufacturer had not received any complaints related to the products covered under the scope of this inspection. The procedure for handling complaints was reviewed. The relevant procedure for product recall was also reviewed. All complaints received would be responded to within 7 days.

8. Change Control

The procedure for process change control number was in place. Changes were categorized into minor, major and critical. A change control form was in place. Changes were reviewed. The issues raised under this section were satisfactorily addressed by the manufacturer.

9. Design and development of products

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

10. Support

Infrastructure and work environment

The infrastructure at the sites were well maintained. The manufacturing environments were well planned, maintained satisfactorily and appeared to be clean and tidy. The work environment was found adequate with personnel wearing suitable PPE. MSDS were available.

Monitoring and measuring resources.

Equipment were identified with unique equipment numbers. The equipment had calibration status labels. An equipment calibration schedule and maintenance records were in place. The calibration records of selected equipment were reviewed. The issues raised under this section were satisfactorily addressed by the manufacturer.

11. Production and service provisions

Control of production and preservation

The manufacturer had 2 warehouses at this location. One warehouse was for storage of yarn and the other was for storage of chemical raw materials. The procedure for receipt and inspection of raw materials and packaging materials and accessories was reviewed. The yarn was sampled and tested for denier, number of filaments, tenacity, elongation etc. The sampling criteria were defined. All the chemical raw materials were supplied by BASF. The raw materials were supplied with a Certificate of Analysis (CoA).

Empty bottles were collected from various parts of the country and transported to the site for recycling. The manufacture of GreenNet involved sorting of the plastics to ensure that only PET bottles were recycled. The process involved washing of the plastics, removal of metals, extrusion, spinning, warping, knitting, coating, curing, cutting and stitching. The sorting and washing of the bottles was carried out on the washline. The test method for determination of PET bottles flakes density was reviewed. The test method for sieve analysis of PET bottle flakes was also reviewed. The sampling plan for flakes was in place. The flakes were sampled and tested for PVC content. The procedure for determination of PVC content in PET flakes was also in place. The yarn warping, tension and setting measuring record and beam card were reviewed.

The flakes were then melted, filtered and subjected to an extrusion process to produce fully drawn yarn (FDY). The spinning parameter register was in place. The yarn was then knitted to make fabric that was then coated.

The manufacture of interceptor G2 involved the preparation of the coating solution, coating, curing, cutting and stitching. The coating solution was prepared following a documented recipe. RO water was used for the preparation of the coating solution. The mixing tank had inbuilt load cells. The stenter temperature and fabric measurement record was reviewed. The RO water generation plant was inspected.

The quality control laboratory performed both physical and chemical tests of both in-process and finished product samples. The Quality Control Laboratory was mostly well-maintained and clean. Chemicals were stored in the chemical storage area of the laboratory. The laboratory equipment was uniquely identified and calibrated. A sample register was in place. The procedure for the determination of Alphacypermethrin by Gas Chromatography in LLIN/Filaments was reviewed. The procedure for handling of test failures was also reviewed. The test report and raw data for DuraNet Plus were reviewed. The in-process quality control laboratory sample book that was used for recording sample parameters such as mesh density and GSM was in place. The manufacturer had a procedure available for the cleaning of glassware. Production and laboratory analysis data was backed up daily. The users had unique passwords and login IDs into the GC software. The date and time on the computer used for GC analysis were locked.

The manufacturer had a Zero waste discharge policy. The waste water was recycled at the Effluent Treatment Plant. Certificates of analysis of the water generated following treatment of the waste were in place. The issues raised under this section were satisfactorily addressed by the manufacturer.

12. Retention samples

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.

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

The manufacturer had a documented process for supplier control. The relevant procedure - Supply chain/Stores was reviewed. The chemical raw materials used for the manufacture of Interceptor G2 were supplied by BASF. The criteria for evaluation of suppliers were defined. Supplier evaluation was once conducted annually. An approved vendor list was in place. Supplier evaluation records for selected suppliers were reviewed.

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 **Shobikaa Impex Private Ltd** 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. 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/