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20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Sheikh Noor-ud-Din & Sons
Corporate address of manufacturer	Moon Netting FZCO Plot No. MO0659 Street 200/202 Jebel Ali Free Zone Dubai, UAE
Inspected site	
Name & address of inspected manufacturing site(s)	Sheikh Noor-ud-Din & Sons 4km, Kanha Kacha Road, off Ferozepur Road Lahore, Pakistan
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	26 – 28 September 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	Sheikh Noor-ud-Din & Sons was established in 1973 and was engaged in the manufacture of Long Lasting Insecticide Nets (LLIN). Since the last WHO inspection, a new line for the manufacture of Polyethylene nets had been installed. Sheikh Noor-ud-Din & Sons manufactures Tsara boost, Tsara, Tsara Soft and Tsara Plus on contract for Moon netting FZCO. The products are released by Moon netting FZCO. The manufacture of Polyester nets involved coating, heat setting, cutting, sewing, labelling, and packaging. The manufacture of Polyethylene nets involved extrusion, warping, knitting, heat setting, cutting, sewing, labelling, and packaging. At the time of the inspection, a transition in ownership was underway. Plans were already in place to sell Sheikh Noor-ud-Din & the PQ

	products. The new prospective owners Pak Poly Products (PPP) intended to acquire and maintain the products on the PQ scheme.
General information about the company and site	The site held an ISO 9001 certificate. ISO 9001 certificate number AQP-10767. Issued 25 June 2022 Valid until 14 May 2023. Scope: ''Manufacturing and export of Long Lasting Insecticidal Mosquito Netting''. The certificate was issued by Quality Registrar Systems International. The site also held an ISO 17025:2017 certificate. ISO/IEC 17025 certificate number LAB 108. Issued: 28/7/2022 Valid until 27/7/2025. The ISO 17025 certificate was issued by the Pakistan National Accreditation Council.
History	The facility was last inspected on 18th – 20th September 2019 by the WHO PQ Inspection Services. The following are some of the major changes since the last WHO inspection: • Installation of ERP. The ERP software was still in the implementation stage. It was being used in the production areas (stenters) and Laboratory. It was also being used for product release. • ERP test run in-store, cutting, sewing production areas & Warehouse was ongoing. • A new line for the manufacture of Polyethylene nets had been installed.
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	Not applicable. The site was not involved in design and development activities.
Out of scope	The manufacture of other LLINs and products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• Tsara Boost (*Deltamethrin 120mg /m^2 ± 25%, Piperonyl butoxide 440mg/m^2 ± 25%*)- 028-001 • Tsara Net *(Deltamethrin 92.5mg/m^2 ± 25%)* - 028-002 • Tsara Soft *(Deltamethrin 80mg/m^2 ± 25%)* - 028-003 • Tsara Plus *(Roof Panel - Deltamethrin 120mg/m^2, Piperonyl butoxide 440mg/m^2 ± 25% incorporated, Side Panel – Deltamethrin 100mg/m^2 ± 25%* - 028-004
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
RPN	Risk Priority Number

Part 2	**Brief summary of the findings and comments**

1. Organizational roles, responsibilities and authorities

An organogram was in place. The Head – Stenter (Polyester), Head – Cutting and Packing, and Head – Textile (Polyethylene) all reported independently to the Plant head. Job descriptions of the Chief Executive Officer (CEO) and the Manager – HR and Compliance were reviewed. The Manager- HR and Compliance had been appointed as the Management Representative and was responsible for ensuring that the quality management system conforms to the requirements of the ISO 9001 standard, on the performance of the quality management system and opportunities for improvement and ensuring the promotion of customer focus.

2. Quality policy and quality objectives

The quality policy included commitments to satisfy applicable requirements and continual improvement of the quality management system. The quality objectives were measurable, monitored, and consistent with the quality policy. Indicators, monitoring and analysis strategies had been defined for each of the quality objectives. The quality policy and quality objectives were displayed at various locations throughout the facility. The quality objectives and quality policy were communicated to employees through training.

3. Management review

Management system procedure for management review meetings was discussed. The purpose of this procedure was to coordinate and control the activities of the QMS and review the performance of the QMS at regular intervals. The procedure stated that the MR should be conducted at least once a year. Unscheduled meetings may be called at any time at the direction of the CEO. The MR is chaired by the CEO and attended by the manager of HR & compliance, head of quality management, GM production, engineering & facilities, store head, manager of finance and lab head. The agenda of the meeting was prepared by the manager compliance which included inputs of various QMS elements and output. The minutes of the MRM were reviewed. The meeting was led by the plant head and attended by the heads of the departments. The QA and QC managers presented the results of activities and confirmed that the range of the product specifications was within the values given by Moon Netting. Other agenda items discussed included complaints, customer feedback, nonconformance, corrective actions, the performance of external providers, process performance, product conformances, adequacy of resources, results of external/internal audits and areas for improvements.

4. Leadership

Top management promoted the improvement and ensured that the quality management system achieved its intended results through management reviews, internal audits, training Correction and corrective actions. Top management had established a quality policy and quality objectives. Top management had established quality policy and quality objectives. The quality objectives were reviewed in management review meetings.

5. Control of documented information

The procedure for control of documented information was reviewed. Documents were categorized as follows:

Level 1	Quality Policy, Quality Objectives, Scope of the quality management system and Quality Manual
Level 2	Management system procedures
Level 3	Other SOPs, work instructions and Job descriptions
Level 4	System forms and formats developed for maintaining records for creating objective evidence of activities.

Level 1 and Level 2 documents were approved by the CEO. Level 3 documents were approved by the Plant Head e.g., operations and other related documents. The management representative was responsible for reviewing documents prior to the approval of the CEO or Plant head. Heads of the department were responsible for the control of documents related to their sections. A list of external documents was in place. Documents were in both hard and soft copy forms. Laboratory generated documentation was backed up daily. Batch production data was scanned and backed up on the server. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

6. Personnel competence and training

The procedure for human resources (HSNDS/COMP/MSP-008 revision 02) was discussed. The procedure stated that before starting any work related duties, the staff should be familiar with all work related documents such as procedures, instructions, and applicable manuals. The procedure also stated that competency requirements should be determined and accordingly personnel should be hired. The new employees are required to receive orientation whereas continual identification of training needs was based on the new requirements as well as changes to the existing procedures and requirements. The training was also evaluated through practical demonstration or written exam. A training plan for 2022 was available which has identified training on various topics for different departments. The attendance sheet as well as the training material for a specific training were available.

7. Risks Management

The procedure for risk management was discussed. The failure mode & effect analysis (FMEA) tool was used for the identification and management of risks. The scope of the procedure extended to each department relating to QMS. The procedure stated that FMEA was conducted whenever there was a change in the process, induction of new technology, a major change in a technical hierarchy or reviewed annually. RPN was calculated using the severity, probability, and detection. The RPN below 50 was acceptable whereas RPN between 50 and 65 required corrective action over a period, RPN between 65 and 80 was categorized as ‘‘risk considerable’’ and required immediate attention and the RPN above 80 required urgent attention including stopping the process.

8. Control of changes

The procedure for change management was discussed. The objective of the procedure was to guide planning, execution, implementation, and evaluation of the effectiveness of any change. The management representative was responsible for assessing the impact of changes. Changes were categorized as Major, Medium, and Minor. Changes were reviewed. Effectiveness of the changes was verified by the Management representative.

9. Internal Audits

Management system procedure for internal auditing was reviewed. The purpose of the internal audit was to provide system for conducting internal audits to determine whether defined activities comply with planned arrangements and identify any gaps and areas for improvement. The scope of the procedure was applicable for all functions in activities related to QMS. The audit plan was approved by the CEO and his deputy. The list of internal auditors was available. The internal audit schedule for 2021-2023 was in place. The Management Representative was responsible for planning and scheduling internal audits. A detailed audit plan was shared by the Management Representative with all responsible personnel. The audit was performed against the ISO 9001:2015 requirements. The internal audit report provided details of audit objectives, scope, audit criteria, findings, and conclusion.

10. Control of nonconforming products

Control of non-conforming outputs was described in the quality system manual. The procedure stated that non-conforming products and services were identified, segregated, and controlled to prevent their unintended use or delivery to the customer. Authorities for the review and disposition of nonconforming products and services were specified. Nonconforming products and services could be accepted by customer concession or reworked to achieve performance. If nonconforming products and services are reworked, they are subjected to re-verification. If nonconforming products and services were detected following delivery to the customer, the company would initiate measures commensurate with the actual or potential effects of the non-conformance.

11. Performance evaluation

The monitored parameters have several quality attributes and process parameters. These included active ingredient content, GSM, mesh size and defects, and percentage of chemical pick-up. The defects monitored included the number of holes, open seams, stains, broken stitches, uneven length etc. the monitoring of these parameters was performed using graphical representations. Upper and lower control limits had been defined for each of these parameters.

12. Design and development of products

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

13. Support

Infrastructure and work environment

The site was generally adequately maintained. MSDS were in place. Safety measures were also in place. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Monitoring and measuring resources

The calibration records of the pH meter, balances, pressure gauges, and temperature gauge were reviewed.

14. Production and service provisions

Control of Production

The manufacture of Polyethylene nets (Tsara, Tsara boost and Tsara Plus - roof) involved extrusion, warping, knitting, heat setting, cutting, sewing, labelling, and packaging. Using an automatic dosing system, the quantities of the different ingredients were extruded. The automatic dosing system was equipped with a Programmable logic controller (PLC). The temperatures of the zones of the extruder and cooling water bath were monitored and maintained. The diameter of the filaments was also monitored. The stretch ratio between take-up and stretching rollers was monitored. The filaments were then wound onto bobbins. This was followed by warping and knitting. The yarn was wound onto beams. The warping and knitting records were maintained. The knitted fabric was then heat set. The temperatures of the stenters were monitored and records were maintained. In-process checks performed on the knitted fabric included GSM and mesh size. In-process test records were maintained in the ERP software. The knitted fabric was then cut, sewed, labelled and packed as per customer requirements.

The manufacture of Polyester nets (Tsara soft and Tsara Plus – Side) involved coating, heat setting, cutting, sewing, labelling, and packaging. The coating solution was prepared by mixing Deltamethrin technical materials with water and other ingredients. The water used for the preparation of the coating solution was generated by the use of reverse osmosis technology. The pH and temperature of the mixture were monitored, and records were maintained. Mixing instructions were in place. The pressure of the pads, pick up of coating solution and temperature of the different chambers of the stenters were monitored. In-process checks performed on the knitted fabric included GSM, mesh size and width. This was then followed by heat setting, cutting, and sewing packaging and labelling.

For products, Tsara Boost and Tsara Plus roof, the fabric was made up from 2 distinct filaments of which one is Deltamethrin dominant and one PBO dominant. On the knitting machine the ratio of the filaments determines the chemical properties of the fabric and is controlled and monitored.

Laboratory samples were registered in the ERP. Information on the batch number, product name, where the sample was collected from, sampling date etc. was recorded. Freshly prepared solutions were adequately labelled. The concentration of active ingredient contained in the coated nets (Tsara Soft and Tsara Plus – Side panel) was determined by the use of HPLC. Usage logs for columns and balances were in place. The date and time on the computers were locked.

Product specifications

The following specifications were reviewed:

1. Tsara Soft
2. Tsara Boost
3. Tsara Net
4. Tsara Plus

At the time of the inspection, testing was being performed on polyester LLIN only and it is being done by the in-house laboratory. For polyethylene (i.e., Tsara net, Tsara boost and Tsara Plus – roof) the testing was carried out by an external laboratory. For GSM, the in-house laboratory was using ISO 3801 (textiles – woven fabrics). For the bursting test, ISO13938-2 was used to test the bursting properties of the fabrics. For the determination of mesh count, based on the WHO recommendation, the in-house laboratory developed the determination of mesh count was used. The determination of deltamethrin content in polyester netting procedure was in place. Test reports for Tsara Boost LLIN from Biolytrics Vietnam Co. Ltd was also reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Interlaboratory comparison (ILC)

The laboratory had been participating in the interlaboratory comparison for tests such as the weight of the fabric (for woven and knit) and the construction of the fabric (for woven and knit). In 2021, the laboratory participated in ILC and z scores for the above tests were well below ≤1.5 thereby demonstrating competency in performing these tests.

Method validation

Method validation records (HSNDS/LMS/FRM-135 revision 00 dated 01/01/2020) were discussed. The validation has covered four parameters such as specificity, linearity, precision, and recovery. The specificity test confirmed the elution times and that there was no interference. In general, the analytical method used for the determination of deltamethrin content in polyester netting was found adequate.

The in-house laboratory was yet to perform testing on polyethylene nets as training, method verification, and a comparison between HSNDS and Biolytrics were still pending.
Batch production records and validation reports for the newly installed Polyethylene line (extruder) were reviewed. Batches were released by a representative of Moon netting following the review of the production and laboratory data.

Wastewater generated from production was treated at the factory. The facility had a waste treatment plant. The wastewater was tested monthly. A copy of the wastewater analysis report was checked. The water was tested by a third-party company.

Identification and traceability

The batch records allowed for the traceability of raw materials and equipment used in production.

15. Preservation

Inventory control was managed by use of the ERP software. Upon receipt of the raw materials, the quantities were verified. All the chemical raw materials were received along with the Certificate of Analysis (COA). The status of the raw materials was indicated. Rejected materials were placed in a dedicated area.

16. Post-delivery Activities

Retention samples were stored dedicated area. The temperature of the retention sample storage area was monitored, and records maintained. The samples were adequately labelled. The samples were retained for six years.

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

Management system procedure for supplier evaluation for external providers was discussed. It was noted that there was hardly any production for the last three years hence procedures were not routinely used. The suppliers were qualified once every three years and preference was given to ISO certified suppliers. The new suppliers were monitored for their performance once every 6 months. A scoring system was in place wherein suppliers were graded in A (scope 32 or more), B (hold for 6 months) and C (totally rejected). A flow chart for approved suppliers was part of the procedure. The suppliers with more than 32 scorings were approved for 3 years.

List of strategic & critical suppliers was also available. The supplier evaluation form described the general requirements as well as quality management system requirements for assessment purposes. Supplier evaluation reports 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 ***Sheikh Noor-ud-Din & Sons*** located at ***4km, Kanha Kacha Road, off Ferozepur Road Lahore, Pakistan*** 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/