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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	Gaotang Xingyuan Textile Factory
Corporate address of manufacturer	The Wind Road South Middle, Gaotang County Economic Development Zone, Liaocheng City, ShanDong Province, China
Inspected site	
Name & address of inspected manufacturing site(s)	As Above.
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	15 May 2019
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	Gaotang Xingyuan Textile Factory only manufactures Long lasting insecticide nets (Yorkool LN). No other brands of insecticide treated nets or products were manufactured at the site. Activities related to manufacture of LLIN included warehousing (storage) of raw materials and finished products, cutting and sewing of the fabric, quality control testing, labelling and packaging.
General information about the company and site	Gaotang Xingyuan is a contract manufacturer (since 2016) for Tianjin Yorkool International Trading Co., Ltd, Lixian County Sangyuan Industrial Zone Baoding City Hebei Province, China. Gaotang Xingyuan Textile Factory, The Wind Road South Middle, Gaotang County Economic Development Zone was ISO certified. ISO 9001:2015 certificate: Date of reissue 12th September 2018, Expiry date 16th August 2020; Certificate number 30717Q20320R0M. Issued by BAC. Scope: Bed net processing and sale services.

	The quality management system (leadership structure, role and responsibilities, policies, procedures etc.) at Gaotang Xingyuan Textile factory was similar to that at Tianjin Yorkool International Trading Co., Ltd.and Bazhou Jintong Textile Processing Factory
History	This was the first WHO audit of the site
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	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	Yorkool LN (Deltamethrin 55mg/m^2) Product number: 021-001
Abbreviations	**Meaning**
CoA	Certificate of analysis
PPE	Personal Protective Equipment
LLIN	Long Lasting Insecticide treated Nets
GSM	Grams per Square Meter

Part 2	Brief summary of the findings and comments (where applicable)

1. Organizational roles, responsibilities and authorities

The manufacturer had a Quality Manual that detailed the responsibilities and roles of the General Manager and Management Representative. The roles of the different departments were also defined. There was an organogram showing the structure of the company. The quality department and production department were independent of each other with separate reporting lines to the Management Representative. The job description of the QA manager was reviewed.

2. Quality policy and quality objectives

The quality policy and quality objectives were documented in the Quality Manual. The quality policy and quality objectives were displayed throughout the premises in the local language and English and were communicated to staff during induction and QA training. The quality objectives were consistent with the quality policy. The quality policy included a commitment to continual improvement. Measurable key performance indicators had been defined for each quality objective.

3. Management review

The requirements for management review inputs and outputs were adequately documented in the procedure for management review. Management review meetings were held once a year. The minutes of the management review demonstrated compliance with the ISO 9001: 2015 requirements for management review. The quality objectives and policy were also reviewed. Performance reports from the different departments were discussed in the management review.

4. Leadership

It was evident from the information reviewed during the inspection that Top Management was committed to the development and implementation of the quality management system. Top Management had approved the quality policy and quality objectives. The General Manger and Management Representative were responsible for the establishment, implementation, maintenance and improvement of quality management system according to the requirements of ISO9001:2015. 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 at the Management Reviews. Top management engaged, directed and supported personnel in fulfilling their responsibilities and roles.

5. Control of documented information

Procedure for document control was in place. Documents were categorized into management documents, technical documents and documents of external origin. The procedure described how documents were to be prepared and identified. Documents were available in both as electronic and hard copy. The general manager was responsible for approving the quality policy and objectives. Heads (Chief) of technical departments were responsible for reviewing technical documents related to their departments. Technical documents were approved by the Management Representative. Documents were distributed by the quality department. The document distribution list was in place. Documents were retained for 4 years.

6. Personnel competence and training

The procedure for training was reviewed. Training programs included training on quality and objectives among others. Trainings were conducted as planned and training records were available. Training records on control of nonconforming products were reviewed. Effectiveness of the trainings was evaluated.

7. Risks and opportunities

The procedure for Risk and Opportunities was in place. The procedure described the risk management process. Risks were to be reviewed at least once a year. A risk register detailing external and internal risks was in place. The risks were scored according to the procedure and allocated Low, Medium or High category.

8. Control of changes

A procedure for change management was reviewed. Changes were categorized into management changes, equipment and production process changes, document changes, regulatory/ISO standard changes and raw material supplier changes. The template of the change application form was in place. The procedure provided for impact assessment of change prior to approval and implementation. Changes were reviewed by the relevant department and approved by the management representative. No change had been registered.

9. Internal Audits

The procedure for internal audits was reviewed. Internal audits were conducted at least once a year. Audit programs were planned, implemented and maintained. The report for the audit conducted on 18th and 19th July 2018 was reviewed. The audit criteria and scope were defined. All the departments were audited. Audit results were reported to the relevant Heads of department. Appropriate corrections and corrective actions had been implemented.

10. Control of non-conforming products

The procedure for control of nonconforming products was reviewed. Defects were categorized as critical, major or minor based on the impact on the quality of the product. The management representative was responsible for managing investigations related to non-conforming products. The procedure allowed for rework of repairable defects, recall of non-conforming products. Any recalled non-conforming products were to be quarantined and records maintained. No products had been rejected by the time of the audit.

The manufacturer had a number of measures in place for quality control and detection of nonconforming products such as quality control checks for height, width, length and visual inspection of sewn bed nets and received fabric for defects such as holes, stains etc. All the received fabric was inspected. Bed nets were sampled and visually inspected for defects. Inspection records were maintained.

11. Performance evaluation

Data analysis control procedure was reviewed. The procedure described the data to collected and analyzed by the quality department, supply and marketing, production department, and Human Resource department. Performance evaluation reports were reviewed and found satisfactory.

12. Complaint handling

The relevant procedure was reviewed. Customer feedback including complaints were to be used to improve the quality management system. Customer surveys were conducted every quarter. Feedback included product quality, delivery, product packing, and service delivery. Complaints were to be investigated. Complaints were managed by the management representative. No complaint had been received by the time of the audit. The customer survey reports for the year 2018 were reviewed. Tianjin Yorkool was the company's only customer. From the customer survey report it was indicated that Tianjin Yorkool was satisfied with the performance of Gaotang Xingyuan.

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 production facility was generally clean, well-organized and appeared to be satisfactorily maintained. The work environment was found adequate with personnel wearing suitable PPE.
The infrastructure was considered suitable for the activities undertaken.

Monitoring and measuring resources

Maintenance records for the sewing machine number 11 and calibration certificate for the 3M ruler were reviewed. The equipment such as sewing machines, tapes measures etc were adequately identified, and their status indicated.

15. Production and service provisions

Control of Production

Upon receipt of the coated fabric from Tianjin Yorkool, all the received fabric was inspected for defects such as tears, holes, presence of extraneous material like stains etc. The inspected fabric was then sewed, labelled and packaged. The sewn bed nets were sampled and inspected. The bed nets were sampled in accordance with an established procedure. The quality control checks performed on the sewed bed nets included weight, height, width, length and visual inspection for defects such as presence of stains, holes, tears etc. Only physical tests were performed by the quality control department. The equipment used in testing was identified.
The sewed bed net inspection records indicated the number and type of defects identified. Bed nets with defects were repaired and inspected again prior to approval for packaging. Labels were adequately controlled. The labels were stamped with a number at the back that enabled traceability of the bed net to the batch number of the fabric used and the worker that performed the sewing.

Records of the number of labels issued and used were retained. Label artwork and information was approved by Yorkool prior to printing. The printing of label was subcontracted. Production batch records were reviewed.

The wastes from production were collected another company, Tai Cang San Feng Chemical Fiber Ltd, China that used the waste to produce other products. All the issues raised in relation to this section were satisfactorily addressed.

Identification and traceability

Material were identified, and status indicated.

Release of products and services

Following review of the production and quality control records the bed nets were released to Tianjin Yorkool by the Quality Control Chief.

The finished bed nets were then sampled and tested by Tianjin Yorkool prior to release to the market. The sampling criteria was based on the ISO 2859 standard.

16. Preservation

There were separate ware houses for the finished products and raw materials. Raw material receipt and issuance records were reviewed. The batch numbers and quantities of materials issued were documented. The status of the raw materials was indicated. No raw materials had been rejected. Finished goods and raw materials were stored at ambient temperatures. The impregnated fabric was supplied by Tianjin Yorkool following chemical analysis and approval by Tianjin Yorkool, Baoding City, Hebei, China.

17. Post-delivery Activities

Stability studies were conducted by the contract giver, Tianjin Yorkool International Trading Co., Ltd. Stability studies were not conducted at this facility. Retention samples were retained by Tianjin Yorkool.

18. Control of externally provided processes, products and services

The procedure for Purchase Control was in place. The procedure described the assessment and evaluation of suppliers. Suppliers were categorized into Category A, B or C depending on the criticality of the material supplied. The performance evaluation of suppliers was conducted once a year. Evaluation records 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, ***Gaotang Xingyuan Textile Factory*** located at ***The Wind Road South Middle, Gaotang County Economic Development Zone, Liaocheng City, ShanDong Province, China*** 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/