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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	Huzhou Wuxing Dongren Textiles Co. Ltd
Corporate address of manufacturer	Babaimu Yinjiawei Village, Balidian Town, Huzhou, Zhejiang, China
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	Same as above
Inspection details	
Dates of inspection	22-23 March 2019
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	The activities related to the manufacture of Yahe LLINs at this site which included warehousing, knitting, cutting, sewing and labelling.
General information about the company and site	Huzhou Wuxing Dongren Textiles Co. Ltd; Babaimu, Yinjiawei Village, Balidian Town Huzhou Zhejiang China was ISO certified. ISO 9001:2015 certificate: Valid until 24th August 2019; ISO Certificate number 02816Q11175R0M. Issued by CNAS. Scope: Production and service of mosquito nets. The site acts as a contract manufacturer for Fujian Yamei Industry & Trade Co. Ltd, Building #2-#3, No. 116 Xikou Industrial area, Zhuxi village, Zhuqi country, Minhou District Fuzhou City Fujian Province China. In addition, the site had a business license to manufacture textile materials under license number 913305026866589728 issued by the Zhejiang province business administration authorities.
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 • In-process test reports • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • In-process quality control areas • Raw material and finished goods • Production areas
Exclusions and Non-applications of requirements in the QMS	Design and development were not applicable as the site is not involved.
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	Yahe (*Deltamethrin* 55mg/m^2), Application number 015-001
Abbreviations	**Meaning**
CoA	Certificate of Analysis
GSM	Grams per Square Meter
LLIN	Long Lasting Insecticide treated Nets
QMS	Quality Management System

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

The manufacturer had an organogram in place. A matrix detailing the management responsibilities was also available Job descriptions of the different staff were available in the quality manual. These were reviewed and found satisfactory.

2. Quality policy and quality objectives

There were documented quality objectives and a quality policy in the Quality Manual. The quality policy was appropriate to the purpose and context of the facility. The Quality policy included a statement to satisfy applicable requirements and a commitment to continual improvement of the quality management system. The quality objectives were measurable. Detailed production targets were documented. The policy and objectives are displayed throughout the premises and are communicated to staff during induction and Quality Assurance training.

3. Management review

Management reviews were conducted in accordance with an established procedure. The procedure followed the requirements of the ISO 9001: 2015 standard in terms of management review input and outs. Management review was held once every year. Minutes of the last management review meeting held were reviewed. The management review took into consideration quality objectives and internal audits among others.

4. Leadership

From the information reviewed and the explanations provided senior management was committed to the effective implementation of the QMS. Resources necessary for implementation of the Quality Management System were determined and provided. The manufacturer monitored and measured the ability of the quality management system to meet planned results through management reviews and internal audits

5. Control of Documented information

The relevant procedure for document control was in place. Identification of documents, document structure and document approval process were described. The distribution of documents was controlled and managed by the Head, QA. Document issuance records were reviewed and found satisfactory.

6. Personnel competence and training

The relevant procedure was was in place. Training plan and records for 2018 were reviewed. Training records on calibration and the use of calibrated measuring equipment were reviewed. Training needs had been identified during an internal audit. The effectiveness of the training was measured by means of a test.

7. Risks and opportunities

The relevant procedure for risk management was in place. Risk identification, assessment and evaluation were described in the procedure. A detailed flow chart describing the risk management process was available. The risk assessment report was reviewed. A Strength, Weakness, Opportunity and threats (SWOT) analysis had been conducted to identify the risks and opportunities. From the SWOT analysis a detailed risk register, had been generated covering identified external and internal risks. All risks have been scored according to the procedure and allocated a Low, Medium or High-risk category. Mitigation measures had been provided and target dates for review indicated.

8. Control of changes

The relevant change control procedure was reviewed. Changes were evaluated by the quality assurance department. Impact assessment of any change was performed by the quality assurance department with support and consultation from the other departments prior to implementation of any change. The documented changes were reviewed. The changes were approved by the Head, QA.

9. Internal Audits

The procedure for internal audits was reviewed. Internal audits were conducted once every year. Internal audit schedules for 2018 and 2019 were available. Audits were conducted by qualified auditors. The auditors did not audit their own departments. A checklist was used to verify the implementation of the ISO 9001 standard. Non-conformities were communicated to the audited department heads during the closing meetings and an internal audit conformity report issued. Non-conformances were classified as serious, normal or small. Internal audit report for 2018 was reviewed and found satisfactory.

10. Control of non-conforming products

The manufacturer had in place a procedure for control of non-conforming products. Non-conforming raw materials were to be quarantined and returned to the supplier. Depending on the defect, non-conforming intermediate materials such as the knitted fabric and finished product would be reworked. If reworking of the intermediate products was not possible then the material would be converted into loops or scrap material. Any defects were recorded, and records maintained.

The procedure for product recall number reviewed. When non-conforming finished products have already been delivered to the customer, depending on the nature of the complaint it is decided whether recall is needed or not. The procedure allowed for investigation to be conducted. The Head, QA oversaw the investigations and an investigation report would be maintained. Any recalled products would be quarantined. No recall had yet been made by the time of the audit.

11. Performance evaluation

Performance evaluation reports were provided. The data was collected and analysed monthly. The data collected and analysed included defects such as presence of stains, inaccurate size, open seams etc. The performance evaluation reports were reviewed and found satisfactory.

12. Complaint handling

The procedure for complaint handling was reviewed. Customer satisfaction procedure, Customer satisfaction questionnaire were also reviewed. No complaints had been registered. The manufacturer had not received any complaints by the time of the audit.

13. Design and development of products

Design and development were not applicable. The site was not involved in the activities of design and development.

14. Support

Infrastructure and work environment

There were two buildings on site. One housed the manufacturing operations while the other was an administrative office. Personnel were provided with protective equipment against noise.

Monitoring and measuring resources

Calibration certificates for the digital balance and measuring tapes were in place. Maintenance records for the knitting machines were reviewed and found satisfactory.

15. Production and service provisions

Control of Production

The approved yarn was warped into bobbins prior to knitting. The warping records maintained included roll speed (revolutions/minute), meters, number of rolls among others. Knitting of the fabric was carried out in a dedicated area. The knitting machines were identified. The knitting records maintained included speed, customer name, color, quantity etc. The knitted fabric was inspected, and records maintained. Following the inspection, a knitting transfer record was maintained with records on knitting machine number, weight per knitting machine, incoming quantity, quantity issued, balance etc., prior transfer of the fabric further processing. The fabric was then dyed with the appropriate color as per the requirements of the customer. The dyeing process involved coating of the fabric with color followed by drying using stenter machines. The dying records maintained included customer name, specification, quantity, machine number. The pressure of the rollers and the drying temperature were monitored.

The fabric was cut according to customer specifications. The records maintained included number of pieces cut, quantity in Kgs, defects etc. All the fabric (100%) was inspected for defects such as holes, tears and extraneous material. The fabric with defects such as holes was reworked. In process checks performed on the fabric included GSM and length of the fabric.

The fabric was then sewed and labeled. The sewed bed nets were inspected (100%) for defects. The sewing records maintained included number of pieces sewed, defects identified, number of pieces repaired.

The finished bed nets were sampled and forwarded for analysis by quality assurance department prior to release to Fujian Yamei for chemical treatment (coating) and further processing. The analysis was performed by an external laboratory. Completed production records for Yahe LLIN were reviewed. Certificates of Analysis were available. Some of the test performed included dimensional measurements, color fastness, yarn count, denier, GSM, pH of aqueous extract, bursting strength etc.

The sewed bed nets were then packaged and transported to Fujian Yamei for chemical treatment (coating) and further processing.

Identification and traceability
Materials and equipment were identified.

16. Preservation
Upon receipt, the yarn was inspected for stains, odour, presence of broken yarn etc. Inspection records were maintained. Inventory records were available. Rejected materials would be quarantined and returned to the supplier. There were separate warehouses for the raw materials and finished goods. All the materials in the ware houses were stored at ambient temperatures.

17. Post-delivery Activities
A dedicated area for storage of retention samples was in place. A sample per order was retained. The bed nets were retained for three years. The samples were kept at ambient temperatures. The manufacturer was not involved in stability studies. Stability studies were conducted by Fujian Yamei Industry & Trade Co. Ltd.

18. Control of externally provided processes, products and services

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, ***Huzhou Wuxing Dongren Textiles Co. Ltd***,located at ***Babaimu Yinjiawei Village, Balidian Town, Huzhou, Zhejiang, China*** was considered to be operating at an acceptable level of compliance with ISO 9001:2015.

All the nonconformities 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/