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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	LTC Yamei Rwanda Ltd
Corporate address of manufacturer	Prime Economic Zone-Plot D11 Road 4, Kigali, Rwanda
Inspected site	
Name & address of inspected manufacturing site(s)	Same as above.
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	19-20 November 2019
Type of inspection	Initial Inspection The criteria for the inspection was based on ISO 9001:2015.
Introduction	
Brief description of the manufacturing activities	The facility only manufactured LLIN. The activities related to the warehousing (storage) of raw materials and finished products, manufacturing of FPP, cutting, sewing, labelling and packaging.
General information about the company and site	LTC Yamei Rwanda Ltd launched its operations in May 2019. LTC Yamei Rwanda Ltd manufacturers LLINs under a partnership arrangement with Fujian Yamei Industry and Trade Co. Ltd, China. LTC Yamei Rwanda Ltd was ISO 9001 certified. It held ISO 9001:2015 certificate number 01/RSB/DG/NCD/QCE/19-20; issued 04-09-2019, Valid till 03-09-2022. The certificate was issued by Rwanda Standards Board. Scope: "Manufacture and sale of long-lasting insecticidal mosquito net from reception of polyester treated (with deltamethrin) fabric, cutting, primary packaging, bulk packaging of sewed nets and dispatch". In addition, the site also held a certificate of Domestic Company Registration number 490883, issued on 17-06-2019.

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	Business activity: "Manufacture cordage, rope, twine and netting. Issued by Rwanda Development Board."
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 not applicable. The site was not involved in design and development.
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	WHO application: 015-001 Yahe (Deltamethrin 55mg/m^2 ±25%)
Abbreviations	**Meaning**
BMR	Batch Manufacturing Record
CoA	Certificate of Analysis
GSM	Grams per Square Meter
QA	Quality assurance
QMS	Quality Management System

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Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

Job descriptions of the QMS Coordinator, Head of Quality Assurance and Internal auditor were reviewed. Roles and responsibilities were clearly defined. The organogram defined the organizational structure with clear indication of lines of authority and responsibility. The production unit was independent of the quality assurance unit.

2. Quality policy and quality objectives

The quality policy and quality objectives were documented. The quality policy included commitment to continual improvement of the quality management system and was appropriate to the purpose and context of the organization. Measurable Key Performance Indicators (KPIs) had been defined for each quality objective. The Quality Coordinator and Head, Quality Assurance were responsible for monitoring the extent to which the KPIs had been met. The facility had recently been launched and no commercial production had yet commenced and thus no monitoring and measurement of the KPIs had yet been performed. The quality policy and objectives were displayed in various areas within the facility premises including production areas. They were displayed in both English and the local language. The quality policy was communicated to the staff in meetings and trainings.

3. Management review

The procedure for management review was presented for review. Management review meetings were held at least once a year. Review of the minutes of the management review meeting held on 6/8/2019 showed that management review was conducted in accordance with the requirements of the ISO 9001:2015 standard and that the procedure was followed.

4. Leadership

The quality policy and quality objectives had been signed by the Managing Director. Top Management was committed to the implementation of the quality management system and was accountable for the effectiveness of the quality management system. A process flow chart showing the production process for the manufacture of bed nets was described in the production procedure and Site Master File. Top Management engaged, directed and supported staff to achieve intended quality results through internal audits.

5. Control of documented information

The document control procedure was reviewed. The procedure described identification, approval, distribution, access, retrieval, retention of documents. Documents were approved by the Managing Director. Soft and hard copies of the documents were distributed to Heads of departments. The rest of the staff received only soft copies. Changes were approved by the QMS coordinator. The procedure allowed for impact assessment of changes. No changes had yet been registered. Document distribution list was available.

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6. Personnel competence and training

Trainings were conducted in accordance with the Human Resource and Code of Conduct procedure. Professional trainings could be conducted internally or externally. Effectiveness of training was assessed by either a written or verbal examination. The assessment criteria for trainees was reviewed. Training records on Quality Management requirements were reviewed.

7. Risks and opportunities

Risk analysis and management was described in the Quality Manual. A risk matrix defining the level of risks taking into consideration their probability and severity was available. Mitigation measures were clearly defined. In consultation with the other departments the QMS coordinator was responsible for reporting on risks identified and monitoring the performance of the quality management system.

8. Internal Audits

Internal audits procedure was reviewed. Internal audits were conducted once per year. The audit program, plan and report for the internal audit conducted on 17/7/2019 were reviewed. The results of the audit were communicated to the departmental heads in a meeting. Copies of the internal audit report were shared with the departmental heads. The audit report was compiled by the QMS coordinator. A list showing attendees of the internal audit meeting was available.

9. Control of nonconforming products

The relevant procedure for control of nonconforming products was available. It allowed for segregation and reworking of bed nets. The manufacturer had in place measures for quality control and detection of nonconforming goods including inspection of all (100%) the sewed bed nets prior to packing. The bed nets were visually inspected for workmanship, presence of correct label, height, length, width etc. Records on reworked bed nets following inspection were retained. All the issues raised in relation to this section were satisfactorily addressed.

10. Performance evaluation

The manufacturer had determined the parameters to be monitored, collect and analyzed. These parameters included: dimensions, active ingredient content, weight (g/m^2), bursting strength among others.

11. Complaint handling

The procedure for customer feedback and complaints handling was reviewed. Details of any complaints were recorded on the customer complaints and handling form. Receipt of the complaints was to be acknowledged within 3 days. Depending on the nature of the complaint an investigation team was appointed by the Factory Manager. The procedure allowed for communication of the progress and outcome of the investigation to the complainant. No complaints had been received yet.

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12. Design and development of products

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

13. Support

Infrastructure and work environment

The facility was clean and well organized. The infrastructure was generally well maintained. Workers wore protective gear. Preventive maintenance schedule and records were reviewed. Review of preventive maintenance records indicated that the reported problems were promptly dealt with.

Monitoring and measuring resources

Calibration certificate for the balances were reviewed.

14. Production and service provisions

Control of Production

Upon receipt of treated fabric from Fujian Yamei Industry and Trade Co. Ltd, China, all the fabric was visually inspected for defects such as stains, holes etc. The inspected fabric was then cut sewed, labelled and packaged. All the sewed bed nets were inspected for workmanship and defects such as stains, tears, holes etc. Other quality control checks performed included checks for height, width, length. Inspection, cutting and sewing records were retained. Bed nets with defects were repaired and inspected again prior to approval for packaging. Label information was reviewed and approved by QA.

Only in-process physical quality control tests were performed on the fabric. The physical tests performed included GSM and number of holes per Square Inch. Samples of the fabric used for production and finished bed net were retained for 5 years.

Each batch of the packaged bed nets sampled and tested prior to release. The physical and chemical tests were outsourced. Completed batch production records and laboratory results were to be reviewed by Head, QA prior to release of the batch. All the issues raised in relation to this section were satisfactorily addressed.

Identification and traceability

Materials were identified, and status indicated. All the issues raised in relation to this section were satisfactorily addressed.

Release of products and services

Completed batch manufacturing records bed nets were reviewed and approved for release by the General Manager.

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15. Preservation

Treated fabric from Fujian Yamei Industry and Trade Co. Ltd was received along with a COA. The quantity received was verified along with procurement officers. Inventory control was managed by use of bin cards. The fabric was also weighed at receipt. All the issues raised in relation to this section were satisfactorily addressed.

16. Calibration and equipment maintenance

The facility was clean and well organized. The infrastructure was generally well maintained. Workers wore protective gear. Preventive maintenance schedule and records were reviewed.

17. Control of externally provided processes and products

The procedure for control of suppliers was reviewed. A list of approved suppliers was available. The initial evaluation of suppliers was based on the following: Reputation of the supplier, quality of product/service, price, discount, delivery time and payment terms. Reevaluation was performed at the end of each financial year.

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, ***LTC Yamei Rwanda Ltd***, located at ***Prime Economic Zone-Plot D11 Road 4, Kigali, Rwanda*** 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

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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/

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