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	Sino Africa Medical Devices Co. Ltd.
Corporate address of manufacturer	Plot No. 27-31, 2nd Ring Road, Luzira Industrial Park, Kampala Uganda
Inspected site	
Name & address of inspected manufacturing site(s)	As above
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	01-02 February 2021
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	Sino Africa Medical Devices Co. Ltd was established in 2015. The facility is a contract manufacturer for Tianjin Yorkool International Trading Co. Ltd, China. Sino Africa Medical Devices Co. Ltd manufactures Long-Lasting Insecticide Nets (LLIN) only. The activities related to manufacture of the LLIN included warehousing, cutting, sewing, labelling and packaging of pretreated fabric.
General information about the company and site	Sino Africa Medical Devices Co. Ltd was certified by the Uganda National Bureau of Standards and had an ISO 9001:2015 certificate; UNBS/QMS/0032, valid from 16th April 2019 to 15th April 2022. Scope: "Manufacturing, Selling and Distribution of Yorkool Long Lasting Insecticidal Nets''. Sino Africa Medical Devices Co. Ltd held a Certificate of Suitability of Premises; NDA/PRE/MDV/2227 from National Drug Authority valid till 31/12/2021.

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

	Sino Africa Medical Devices Co. Ltd also held a Trading license certificate number 05/01/2021 valid till 30th December 2021. The trading license was issued by Kampala Capital City Authority, Uganda.
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 • Product release • Batch processing records • Control of changes • Internal audits • Calibration and equipment maintenance **Physical 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 was not involved in the design and development of the product.
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® Long lasting Insecticidal Net (55mg/m^2 Deltamethrin) Product number: 021-001
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
LLIN	Long Lasting Insecticide treated Nets

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities
An organogram showing the reporting structure between managers and departments was in place. The Management Representative reported to the General Manager. The roles and responsibilities of the General Manager and Management Representative were defined in the Quality Manual.

2. Quality policy and quality objectives
The quality policy and quality objectives were defined in the Quality Manual. The quality policy provided the basis upon which the quality objectives were developed and included a commitment to continual improvement. The quality objectives centered around customer satisfaction and conformance of finished products and were coupled with measurable performance targets. The quality policy was displayed within the production and packaging area. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

3. Management review
The Management Review Control Procedure was reviewed. The procedure required that the following inputs to be prepared for discussion: Report on operation status of the quality management system, audit report of the quality management system, customer information feedback and satisfaction report, and report on data analysis results of the implementation of the quality objectives and work summary report of suggestions for improvement. Management Review Meetings were held at least once per year. The minutes of the management review meeting held on the 14/12/2020 were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

4. Leadership
Top management demonstrated commitment to the establishment of the quality policy and quality objectives. The integration of the requirements of the quality management system was noted within the organizations' processes through internal audits and management review meetings.

5. Control of documented information
The relevant document control procedure was in place. It described process for creation of documents within the quality management system. The process for assigning document numbers, titles and version control was described. The distribution, access, retrieval and use of documents was managed by the quality department. Documents were approved and controlled as per the procedure. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

6. Personnel competence and training
The relevant procedure; Training Management System was reviewed. The different categories of trainings including induction training, on-the-job training and professional skills training were defined. The Training Schedules for 2019 and 2020 were reviewed. In the event that planned training activities could not be conducted, a Training Plan Change Form would be completed. Training records were reviewed. Training on Safe Production Responsibility was provided to all staff on the 15/01/2020.

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

7. Risks and opportunities

The risk and opportunity control procedure was available and described the types of risks and opportunities and the criteria for risk evaluation. The Risk and Opportunity Identification, Response Measures Evaluation form that defined the risks and opportunities identified within related processes and relevant departments was reviewed. The impact of the COVID-19 pandemic on the organization was detailed in the Risk Review form.

8. Control of changes

The relevant procedure; Change Management System was in place. It described the types of changes and the responsibilities of each department regarding management of changes. A change regarding the amendment of the Customer Related Process Control Procedure was reviewed.

9. Internal Audits

The Internal Audit Control Procedure was reviewed. The Annual Internal Audit Plan prepared for the audit that was conducted from the 7 – 8 December 2020 was reviewed. The plan documented the purpose of the audit, identified the ISO 9001:2015 standard as the basis for the audit. The internal audit report was reviewed. Training records of the internal auditors were also reviewed.

10. Control of nonconforming products

The procedure for control of nonconforming products was reviewed. The procedure was applicable to nonconforming products purchased by the company, nonconforming products identified during the production process, inspection and delivery.
Customer complaints were collected by the sales department. Customer complaints were reported to the quality department which was responsible for handling customer complaints. The procedure provided for investigations. No complaints had been received by the manufacturer at the time of the inspection. The procedure for control of nonconforming products also described the handling of recalls. No recalls had been instituted by the time of the inspection.

11. Performance evaluation

Parameters to be monitored and measured had been determined. The performance and effectiveness of the quality management system was monitored through internal audits, customer satisfaction surveys, monitoring of production parameters such as such as length, width, height, stains, holes etc. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

12. Design and development of products

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

13. Support

Infrastructure and work environment

The facility was well maintained and clean. The work environment was found adequate with personnel wearing appropriate protective gear PPE. Cleaning records were available.

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Monitoring and measuring resources

Equipment were identified and calibration status labels available. The calibration schedule was reviewed. Calibration certificates for the measuring tape and weighing scale respectively were in place. The sewing machine checklist was also reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

14. Production and service provisions

Control of Production

The manufacture of Yorkool® Long Lasting Insecticidal Nets involved cutting, sewing, labelling and packaging of pre-treated fabric from Tianjin Yorkool International Trading Co. Ltd, China. All the pre-treated fabric was visually inspected for defects such as holes, stains etc. The inspected fabric was then cut, sewed, labelled and packaged according to customer specifications. Measuring tapes used to measure the length of the fabric to be cut were calibrated. The sewed bed nets were sampled and inspected for workmanship and defects such as stains, holes etc. Other quality checks performed included checks for height, width length of the sewed bed nets. Inspection records at the different production stages were maintained. Records of label issuance and usage were available. Bed nets were packaged manually. Batch production records were reviewed.

Finished bed nets were sampled and inspected for physical defects. The sampling criteria for the sampling of finished bed nets was defined in the Inspection standard of finished mosquito nets. Inspections records were maintained. A sample per batch was sent to Tianjin Yorkool International Trading Co. Ltd, China for both physical and chemical testing. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

Material were identified, and status indicated. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Release of products and services

Batches were released following the review of production data and CoA of the finished bed nets from Tianjin Yorkool.

15. Preservation

On receipt of raw materials including treated fabric; information on the packing list such as the quantity, batch number, and other specifications was verified. The procedure for Warehouse Management System describing the handling of raw materials in the warehouse was in place. Inventory control was managed by use of stock cards.

16. Post-delivery Activities

Retention samples were stored in a dedicated area. A sample of each batch of the finished products was retained. The samples were adequately labelled. The samples were stored at ambient temperatures.

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

17. Control of externally provided processes, products and services

The Purchasing control procedure described the evaluation, selection and monitoring of suppliers. The evaluation of suppliers was performed once a year. The critical suppliers list was in place. The 2018 supplier evaluation report for Tianjin Yorkool International trading Co. Ltd was 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 ***Sino Africa Medical Devices Co. Ltd*** *located at* ***Plot No. 27-31, 2nd Ring Road, Luzira Industrial Park, Kampala, Uganda.*** 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/