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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	China Jiujiang Health Tex Industries Co., Ltd
Corporate address of manufacturer	Mainpol GmbH Daimlerstrasse 10 73095 Albershausen. Germany.
Inspected site	
Name & address of inspected manufacturing site(s)	China Jiujiang Health Tex Industries Co., Ltd. West Zone of Industrial Park, Dean County, Jiangxi 330400, China
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	15 – 17 May 2023
Type of inspection	Special (Investigative) The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	The activities related to the manufacture of SafeNet included preparation of the chemical solution, coating, stentering, cutting, sewing and packaging.
General information about the company and site	The facility is situated within an industrial park where a variety of manufacturing activities are carried out by different companies. China Jiujiang Health Tex Industries Co., Ltd exclusively focuses on the production of polyester nets, under contract for Mainpol. Despite the sharing of some facilities within this park, China Jiujiang Health Tex Industries Co., Ltd has distinct, segregated workshops dedicated to its polyester net manufacturing. Clear operational separation from other manufacturing activities is in place, such as the production of polyethylene nets by another company. This delineation of manufacturing spaces for polyester and polyethylene nets has been effectively maintained since the last inspection.
History	This was the second WHO inspection of this facility . The facility was last inspected in August 2019 by WHO.

	All the previous nonconformities had been addressed. The site was certified as indicated below: **ISO 9001: 2015: Quality Management System** Certificate Number: R306Q09456 Issue Date: 26 May 2022 Expiry Date: 25 May 2025 **Scope:** Production of Mosquito nets The certificate was issued by Shenyl Inspection & Certification Co. Ltd. **ISO 14001: 2015: Environmental Management System** Certificate Number: R306E03328 Issue Date: 03 April 2023 Expiry Date: 08 June 2026 **Scope**: Production of Mosquito Nets The certificate was issued by Shenyl Inspection & Certification Co. Ltd. **ISO 45001: 2018: Occupational Health and Safety Management System** Certificate Number: R306S09457 Issue Date: 26 May 2022 Expiry Date: 25 May 2025 **Scope:** Production of Mosquito Nets Production and sales of textiles (Mosquito nets, Long Lasting mosquito Nets) The certificate was issued by Shenyl Inspection & Certification Co. Ltd.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review included but was 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	Design and development activities were not undertaken at this site. Design and development was undertaken by Mainpol. This section is therefore not applicable.
Out of scope	The manufacture of other products not submitted to WHO Prequalification were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	SafeNet - 018-001 - Alphacypermethrin - 6.7g/kg for 75D, 5.0 g/kg for 100D
Abbreviations	**Meaning**
CoA	Certificate of Analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System

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

1. Quality policy and quality objectives

The quality policy and quality objectives were documented in the Quality Management Manual. The quality objectives were related to the following: product inspection, customer satisfaction, solid disposal rate, safety, fire and electric shock, mechanical injury accidents, and occupational diseases. The quality objectives were monitored and measured across all the departments. The progress on achievement of the quality objectives was conducted monthly. The quality policy included a commitment to continual improvement of the quality management system. The quality policy and quality objectives were displayed in production areas and were also communicated through trainings. Training records on the Quality policy and objectives were available.

2. Management review

Management reviews were held at least once a year. Management review minutes were reviewed. Leaders, executive office, purchasing department, production department, QC, finance department participated in these management reviews.

The agenda included:

- Suitability, adequacy, and process effectiveness of the integrated management system

- Degree to which product and services meet the requirements of customers and relevant parties
- The quality, environmental performance and occupational health safety of the organization
- Integrated management policy and objectives
- Degree of resource demand and requirements
- Opportunities to improve product quality and service, environment and integrated management
- Customer satisfaction and feedback
- Actions from previous management reviews
- Achievement of Management objectives
- Results of internal audits
- Performance of external suppliers
- Adequacy of resources and
- Effectiveness of measures taken to address risks and opportunities
- Non-conformity control and corrective measures

Opportunities for improvement had been identified and quality objectives had been met. Management review was found satisfactory.

3. Organizational roles, responsibilities, and authorities

An organizational structure indicating the hierarchical and reporting lines was in place. The job responsibilities and roles of the different key positions were documented.

4. Control of documented information

The document control procedure was reviewed. The procedure described the identification, control of document changes, approval, issuance and retention of documents. A distribution list of documents was available. Document changes were reviewed. The changes were reviewed and approved as per the procedure. Documented information was to be retained for four years. Records were maintained in hard copy formats.

5. Personnel competence and training

The relevant procedure on training and evaluation of effectiveness of the staff was available. Training and evaluation records were reviewed and found acceptable. An employee training plan was available. Training on various procedures was given to different workers from different departments/units (cutting, sewing, management etc.). The training included trainings on quality, environment and occupational health and safety, timelines etc.

Training records of staff on ISO45001:2018, GB/T19001-2016/ISO9001:2015 were available. Training records and evaluation forms were available. The attendance list of participants was also available.

6. Risks Management

The procedure for risk management was reviewed. Each department was involved in risk identification and assessment. The criteria for the assessment of risks was defined. A risk register was also in place. The risk related to the following area among others were assessed: Warehouse, process job controls, product size and failure, machine performance, laws and regulations, Human errors, packaging and inspection, equipment operations etc.

7. Control of changes

The procedure for change management was reviewed. Change request forms were in place. A change related to revision of the quality policy was reviewed. This change was handled in accordance with the procedure.

8. Internal Audits

The relevant internal audit procedure was reviewed. The procedure described the scope, methods, responsibilities, planning and reporting of internal audits. Internal audits were conducted at least yearly. Checklists were used for internal audits. The report format was also described. To ensure objectivity and impartiality of the audit process the auditors did not audit their own areas of work. An internal audit plan for 2023 was in place. The internal audit reports were also available.

9. Control of nonconforming products

The relevant procedure for control of nonconforming products was discussed. The procedure was applicable to procurement of materials, safety protective equipment, nonconforming products that have been identified during production, delivery, or use. The manufacturer could deal with nonconforming products in one or more of the following ways:

-Reject
-Rework and repair
-Dispose
-Reject and return

A nonconforming product ledger was in place. Records were reviewed.

10. Performance evaluation

The procedure for process, performance evaluation, and measurement control procedure was reviewed. The purpose of the procedure was to ensure effective operation of the quality management system through routine monitoring and measurement of the integrated management systems. The monitoring and measurement of processes was carried out through management reviews, internal audits, work inspections etc. Qualitative and quantitative approaches were used to measure the performance of the quality management system.

11. Design and development of products

Design and development of SafeNet was undertaken by Mainpol. China Jiujiang Health Tex Industries Co., Ltd was not responsible for the design and development of SafeNet and therefore this was not inspected.

12. Customer satisfaction

The procedure for customer satisfaction was reviewed. Customer satisfaction surveys were conducted every six months. The supply and marketing compiled the collected customer information and analyzed it using statistical techniques. Major trends and issues were reported to management representative. Customer satisfaction surveys were conducted using questionnaires. The survey collected information related to quotation and price, quality, packaging, delivery, issuance of inspection report, overall satisfaction of quality product and company's service attitude. The 2023 customer satisfaction survey was reviewed.

13. Complaints

The procedure for handling complaints was reviewed. The quality department was responsible for handling complaints. The procedure applied to customer complaints related to quality of products and the company's management system. A customer complaint sheet was in place. Depending on the nature, the market complaints received by Mainpol were submitted to China Jiujiang Health Tex Industries Co., Ltd for investigation. Complaints received by the manufacturer were reviewed.

14. Contract between China Jiujiang Health Tex Industries Co., Ltd and Mainpol

The contract between China Jiujiang Health Tex Industries Co., Ltd and Mainpol was reviewed. Mainpol as a designated supplier was responsible for supply of the binders. The binders were required to be delivered with a Certificate of Analysis. This was found satisfactory.

15. Contract between China Jiujiang Health Tex Industries Co., Ltd and Jiangsu Gongcheng

The conversion of Alphacypermethrin TC to Alphacypermethrin SC was carried out by Jiangsu Gongcheng. The roles and responsibilities of either party were defined. The contract required that any changes to the preparation of Alphacypermethrin SC be notified to China Jiujiang Health Tex Industries Co., Ltd.

16. Support

Infrastructure and work environment

The procedure for equipment maintenance operations was reviewed. A maintenance plan was in place. Maintenance records of the sewing machines, automatic cutting machine, pool press baler, wrapping machine were also in place.

Personnel were appropriately donned in PPE. Personnel in the chemical weighing and mixing area had eye googles, boots, rubber gloves and gowns.

Monitoring and measuring resources

Calibration certificates for the balances in the chemical weighing area and coating area were reviewed.

17. Production and service provisions

Control of Production and preservation

The activities involved in the manufacture of SafeNet included Coating, heat setting, cutting, sewing labelling, packaging, and baling. The procedure for receipt of raw materials was reviewed. Upon receipt the quantity of the received greige fabric was verified. The fabric warehouse was segregated into qualified and rejected areas. A fabric inspection area was also in place. Inventory was managed by use of bin cards. The chemical raw materials were adequately labelled, and status labels indicated.

The weighing of raw materials was performed following the manufacturing recipe. Each raw material had a dedicated calibrated weighing scale. The chemical raw materials were weighed into dedicated and color-coded buckets. The instruction for mixing were in place. The amount of water added to the mixing tank was verified using dipsticks. The parameters recorded during the coating process included pressure of the rollers, temperatures of the chambers, width of the fabric, GSM, speed etc. The PLC used to monitor the temperatures of the chambers was password protected.

Production flow cards with information on number of the stenter line, order number, fabric weight, color, GSM, trolley number etc. were in place to enable traceability.

Inspection of fabric was performed using both the manual inspection and automatic inspection machine. An automatic cutting machine had been installed and was in use at the time of the inspection. All the sewed nets (100%) were inspected for defects after sewing. Sampling criteria for the finished products was in place. Sampling criteria at the different stages of production such as coating, heat setting, cutting, sewing were defined. At the time of the inspection the manufacture of SafeNet was ongoing.

Quality control lab

The procedure for determination of Active ingredient content was reviewed. The analytical method was based on CIPAC method. The test reports and raw data for analysis of SafeNet were reviewed. The analysis was performed in accordance with the relevant standard testing procedure.

Waste management

The procedure for waste management was reviewed. Solid and liquid waste was collected by a third-party company that was responsible for the treatment and disposal of the waste. A contract dated August 2022 between the third-party company and China Jiujiang Health Tex Industries Co., Ltd was in place.

18. Post-delivery Activities

The samples were stored at ambient temperatures. A sample of every batch was retained. The sample retention records were in place. Samples were retained for a period equivalent to the shelf life of the product plus one year.

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

An approved supplier list was in place. The purchasing control procedure was reviewed. The procedure described the selection and evaluation of suppliers. The criteria for selection of suppliers included:

- Price
- Legality
- Product characteristics meeting relevant requirements
- Meets the needs of company

The performance evaluation criteria included:

- Delivery times
- Services
- Price
- Quality

Evaluations were conducted once a year. Supplier performance evaluation reports were 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 **China Jiujiang Health Tex Industries Co., Ltd** located at

West Zone of Industrial Park, Dean County, Jiangxi 330400, 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. 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/