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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	Dean Superior Textile Co. Ltd
Corporate address of manufacturer	Mainpol GmbH Daimlerstrasse 10, Albershausen, 73095, Germany
Inspected site	
Name & address of inspected manufacturing site(s)	Dean Superior Textile Co. Ltd Baota Industrial Park Zone West, Dean County Jiujiang, 330400 P.R. China
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	8,11 and 12 March 2024
Type of inspection	Re-inspection The inspection was to establish that the applicable requirements of ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	Dean Superior Textile Co. Ltd manufactured Long-Lasting Insecticide Nets (LLIN) on contract for Mainpol GmbH. The activities related to manufacture of the LLIN included warehousing (storage) of raw materials and finished products, incorporation, knitting, cutting, sewing, labeling, packaging, and quality control testing.

General information about the company and site	ISO 9001: 2015: Quality Management System Scope: ‘‘Manufacturing and sale of bed net’’ Certificate Number: CI/141387Q Issue Date: 7 July 2022 Valid until: 6 July 2025 The certificate was issued by Certificate International.
History	The site was last inspected in 2018 by WHO.
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 • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	Design and development of products were not applicable as the site was not involved in the design and development activities.
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• Royal Sentry (Alphacypermethrin 5.8g/kg±25%) – 003-001 • Royal Sentry 2.0 (Alphacypermethrin 5.8g/kg±25%) – P-00210 • Royal Guard (Alphacypermethrin 5.5 g/kg and Pyriproxyfen 208 mg/m^2 for 120 denier LLIN and Alphacypermethrin 5.0 g/kg and Pyriproxyfen 225 mg/m^2 for 150 denier LLIN) - P-00211 • SafeNet Plus (Roof: Alphacypermethrin 5.8 g/kg and Piperonyl Butoxide (PBO) 20.3 g/kg and sides: Alphacypermethrin 5.8 g/kg) - P-09284

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
RPN	Risk Priority Number

Part 2	Summary of the findings and comments

1. Quality policy and quality objectives

The quality policy and quality objectives were documented in the quality manual. The quality policy and objectives were displayed at various areas throughout the facility. The quality policy and quality objectives were also communicated through trainings. Training records on the quality policy, quality objectives, and company's requirements were available. The quality objectives were monitored and measurable. Key performance indicators for each objective were defined. The objectives were related to customer satisfaction, qualified rate of production sampling inspection, rate of produced finished products, zero fire and accidental incidence, rate of safe disposal of solid waste, electric shock incident and zero mechanical accident.

2. Management review

The procedure for management review was in place. The management review meetings were held once annually. The latest management review minutes were reviewed. The meeting was chaired by the General Manager. The meeting was attended by Heads of the different departments. The review took the following among others into consideration the parameters and aspects defined by the ISO 9001 standard.

3. Organizational roles, responsibilities, and authorities

An organogram showing the hierarchical and reporting structure was in place. The responsibilities of the key personnel were defined. Job descriptions of both QC director and QA manager were reviewed. The responsibilities of the different departments were described in the quality manual. The organization demonstrated commitment and leadership with respect to the establishment of the quality policy and quality objectives for the quality management system, promoting improvement and supporting management roles in their areas of responsibility through internal audits, management reviews, implementations of corrections and corrective actions.

4. Document control

The relevant procedure for document control was in place. The procedure described the access, retrieval, storage, and retention of documents. A document control list was also in place. Documents were adequately identified with file names, identification numbers and responsible departments. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

5. Personnel competence and training

The procedure for Human resource management program was reviewed. The procedure described the identification of training needs, how the trainings were to be conducted, evaluation of trainings and how frequently trainings were to be conducted. The training plan for 2023 and 2024 were in place. Training records including assessment of the effectiveness of the trainings were maintained. Training records on quality, environment, occupational health, and safety management system were reviewed.

6. Risk Management

The procedure for risk management was described in the quality manual. The risk management procedure considered internal, external, and corporate factors that affect the company's goals, strategic decision and performance of the management system, quality, environment, occupational health, and safety. A risk assessment register was in place. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

7. Internal Audits

The procedure for internal audits was reviewed. The procedure described the purpose, scope, and management of internal audits. The procedure also described the preparation and conduct of internal audits including follow up of nonconformities raised in the internal audit. An internal audit plan was in place. The 2023 internal audit report was also in place. Corrective actions to the identified nonconformities had been implemented and follow-up was completed. An internal audit checklist, non-compliance report and internal audit meeting records were in place.

8. Control of nonconforming products and complaint handling

The procedure for handling of nonconforming products was documented in the quality manual. Nonconforming products could be handled in one of the following ways:

- correction.
- segregation, containment, return or suspension of provision of products and services.
- informing the customer.
- obtaining authorization for acceptance under concession.

Records on nonconformities were reviewed.

9. Customer Satisfaction and Complaints

The procedure for customer complaint management was reviewed. The quality department was responsible for organizing investigations and providing responses. Complaints were categorized into serious complaints and general complaints. No complaints had been received at the time of the audit. A template of a compliant report was in place.

The procedure for customer satisfaction was in place. Customer satisfaction surveys were conducted using customer satisfaction survey forms (questionnaires). The business department was responsible for conducting customer satisfaction surveys and analysing the information collected. The Customer satisfaction survey for the period January 2022 to June 2022 was reviewed. The survey considered the following: price, quality, delivery on time, packaging, quantity, service attitude etc. A customer satisfaction statistics analysis was in place.

10. Change Control

The procedure for control of changes (SLL/CX-01-04) was reviewed. The procedure described the purpose, scope, types of changes, responsibilities, and management of changes. A list of changes since 2018 was provided. The changes included:

- Increase in the number of personnel responsible for quality assurance to ensure product quality, enhance customer satisfaction, mitigate risks, and ensure compliance with the company production standards.
- There was an expansion in the operations of the facility. There was an increase in the number of products manufactured by the site.
- The addition of a gas chromatograph (GC) in the laboratory to enhance product testing.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

11. Performance Evaluation

The manufacturer analyzed and evaluated the following:

- Conformity of products
- Audit results.
- Customer satisfaction and feedback
- Extent to which quality objectives had been met.
- Nonconformities and corrective measures
- Performance evaluation of external suppliers

These were discussed in management review meetings.

12. Design and development of products

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

13. Support

Infrastructure and work environment

The facility comprised of two main buildings: namely Building A and Building B. Building A housed the manufacturing/processing equipment, yarn extrusion area, knitting area and stenters. Building B housed the warehouse, cutting and inspection area, QA department offices, sewing section, packaging, and baling areas. The knitting area was serviced by a heating, ventilation, and air conditioning system (HVAC). All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Monitoring and measuring resources.

The maintenance records for the heat setting machines were reviewed. The balances and HPLC had valid calibration status labels affixed to them.

14. Production and service provisions

Control of Production

The production of Royal Sentry, Royal Sentry 2.0, Royal Guard and SafeNet Plus involved mixing of the masterbatch with HDPE granules, yarn spinning, warping, knitting, heat setting, cutting, sewing, packaging, and baling. The production areas were inspected though no production was ongoing at the time of the inspection. The inspection team visited the warehouse, production areas and quality control laboratory.

The production records for Royal Guard and Royal Sentry 2.0 were reviewed. The manufacturer had not yet started commercial production of SafeNet Plus. It was stated that there had been no production of Royal Sentry since 2018.

The raw materials were weighed following the approved manufacturing formula. The records for bursting strength, GSM, Mesh Size, Net size, and the inspection record were available. The packaging spot check reports were also in place. The SOP for label control was also reviewed.

The procedure for the preparation of the fabric sample for active ingredient and washing test was reviewed. Analytical test results and raw data for selected batches were reviewed.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

15. Preservation

Inventory records for HDPE, Alphacypermethrin master batch, Pyriproxyfen master batch were available. The records provided details of the batch numbers of the raw materials, quantities received, quantities issued to production, dates of receipt and issue of the raw materials, stock at hand etc. The raw materials were received along with certificates of analysis.

16. Retention samples

Retention sample records for 2023, 2022, 2021 were checked. 8 samples of each batch were retained. The samples were stored at ambient temperatures for 4 years.

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

The procedure for Purchasing and supplier control was reviewed. The procedure described the categories of suppliers, the selection and evaluation of suppliers. The purchasing department was responsible for selection and evaluation of suppliers. An approved supplier list was in place. The supplier evaluation reports for selected suppliers 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 by **Dean Superior Textile Co. Ltd** located at **Baota Industrial Park Zone West, Dean County Jiujiang, 330400 P.R. 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/