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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	Baota Industrial Park West Zone, Dean County Jiujiang City, Jiangxi Province China
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	As above.
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	25-26 October 2018
Type of inspection	Initial inspection. Citeria against which the site was inspected: ISO 9001:2015 standard
Introduction	
Brief summary of the manufacturing activities	Dean Superior Textile Co. Ltd manufactures Long Lasting Insecticide Treated Nets (LLIN). The activities related to manufacture of the LLIN included warehousing (storage) of raw materials and finished products, production of yarn and fabric (incorporation), cutting and sewing, packaging and quality control testing. Only physical quality control tests were performed at the site. Chemical testing of the bed nets was outsourced. Dean Superior Textile Co. Ltd is an equity partner/member of Disease Control Technologies, LLC.
General information about the company and site	Dean Superior was ISO 9001:2015 certified. Certificate number CN13/30987: Date of issue 27th July 2017, Valid until 8th August 2019, Issued by SGS.
History	This was the first WHO audit performed at 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 • Sampling and laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Quality control laboratory • Raw material and finished goods warehouses • Production areas
Exclusions and Non-applications of requirements in the QMS	Design and development were excluded from applications of the ISO 9001: 2015 standard.
Out of scope	Products not submitted to WHO for prequalification
Restrictions	None.
WHO products covered by the inspection	Royal Sentry LLIN (*Alphacypermethrin* 5.8g/Kg ± 25%) - 003-001 Royal Sentry 2.0 (*Alphacypermethrin* 5.8 g/kg± 25%) - 003-002 Royal Guard (*Alphacypermethrin* 5.5g/kg ± 25% for 120 denier yarn and 5.0 g/kg ± 25% for 150 denier yarn. *Pyriproxyfen 5.5 g/kg ± 25 for 120 denier yarn and 5.0 g/kg ± 25 for 150 denier yarn*) - 003-003
Abbreviations	**Meaning**
LLIN	Long-lasting insecticide nets
MSDS	Material safety data sheet
PPE	Personal protective equipment
QA	Quality assurance
QMS	Quality management system

Part 2	**Brief summary of the findings and comments**

1. Organizational roles, responsibilities and authorities

Roles and responsibilities were described in the Quality Manual and supported by a detailed organogram which showed that reporting lines and responsibility for QA separate from production management. Job descriptions were defined. This was found satisfactory.

2. Quality policy and quality objectives

The policy and quality objectives were documented and were considered adequate to the purpose and context of the organization and met the requirements of the standard. The policy was communicated within the organization through noticeboards and during the induction training.

3. Management review

The relevant procedure for management review was in place with management review described in the Quality Manual. The agenda for management review was documented in the quality manual. Management review meetings were held once a year. Management review minutes were reviewed. Among the agenda items discussed were the quality objectives and performance data and reports. Management review was performed in accordance with the established procedure and met the requirements of the standard.

4. Leadership

A statement regarding leadership and commitment was described in the Quality Manual. Leadership commitment with respect to the quality management system was demonstrated by establishing quality policy and quality objectives, promoting improvement and supporting management roles and responsibilities.

5. Control of documented information and changes

The manufacturer had in place a procedure for document control. The procedure adequately described the creation, approval, distribution and review documents. Procedures were maintained as electronic and hard copies. Production records such as knitting reports, inspection reports were maintained. Document control practices were generally compliant with the requirements of the standard. Changes to documentation and processes were to be reviewed. No changes had been registered.

6. Personnel competence and training

The relevant procedure and training records was reviewed. Job descriptions of key employees were also reviewed. No issues were raised.

7. Risks and opportunities

The quality manual had a flow chart that described the requirements for assessing risks and opportunities. The relevant procedure for risk management was reviewed. A risk register was in place. A SWOT Analysis had been performed.

8. Internal Audits

The relevant procedure for internal audits was reviewed. Internal audits were conducted annually. A check list was used for conducting audits. An audit report and corresponding nonconformance report for the audit conducted in June 2018 were reviewed. The audit plan indicated the areas to be audited, audit team members and ISO clauses covered.

9. Control of non-conforming products

The manufacturer verified and inspected bed nets to ensure that defective bed nets were identified and controlled. The manufacturer had documented criteria for assessment of nonconformities such as holes, tears, etc. Repairable defects such as holes were repaired by stitching. The repaired bed nets were inspected again to ensure that they conform to the specified requirements. All nonconformities were documented.

10. Performance evaluation

Key manufacturing processes and quality parameters were monitored. The issues raised related to this section were satisfactorily addressed by the manufacturer.

11. Complaint handling and Customer satisfaction

All complaints are received and managed directly by Disease Control Technologies. No complaints were recently logged.

12. Design and development of products

Design and development were excluded from applications of the ISO 9001: 2015 standard.

13. Support

Infrastructure and work environment

The work environment was found adequate with personnel wearing suitable PPE. MSDS and firefighting equipment were available in warehouse, laboratory and other production areas. The infrastructure was well maintained. An environmental report from Jiujiang Environmental Monitoring station concluded that the facility met the requirements for the environmental management system.

Monitoring and measuring resources

The calibration and maintenance schedule for 2018 was reviewed. The calibration report of the bursting strength tester was reviewed. Equipment maintenance reports for the extruder and stenter were reviewed. These were found satisfactory.

14. Production and service provisions

Control of Production

The manufacturing of the fabric involved blending, extrusion, cooling, presetting, warping and knitting. At the time of the inspection, manufacture of Royal Sentry was ongoing. The temperatures of the drying chambers were monitored and controlled. The documented information included production records, in-process test records, and inspection records etc. The fabric was inspected for defects such as holes, tears, presence extraneous materials at different stage in the manufacturing process. Records on defects were maintained.

Only physical quality control tests were performed onsite. Chemical testing of the bed nets was outsourced to TÜV SÜD PSB Pte Ltd 1 Science Park Drive, Singapore 118 221. The laboratory equipment was uniquely identified and calibrated. Laboratory test records for denier, GSM and bursting strength were reviewed. Completed batch manufacturing records for Royal Sentry bed nets were reviewed. The test results were reviewed by Disease Control Technologies and approved for release to Dean Superior Textile Co. Ltd. At Dean Superior Textile Co Ltd, the products were released by the QA following eview of production data.

No commercial batches of Royal Sentry 2.0 and Royal Guard had been manufactured by the time of the inspection. The issues raised related to this section were satisfactorily addressed by the manufacturer.

Identification and traceability
Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability.

15. Preservation
The temperatures in both the chemical raw material and finished product storage areas were ambient. Upon receipt; the containers of the raw materials were inspected for physical defects. All raw materials were received along with a certificate of analysis. The issues raised related to this section were satisfactorily addressed by the manufacturer.

16. Post-delivery Activities

Storage stability
Prior to the establishment of the WHO Prequalification programme: Vector Control stability studies were conducted with results submitted to the WHO- WHOPES programme for approval. The report addressing these studies was not available on site. To date no other stability studies had been conducted.

17. Control of externally provided processes and products
The relevant procedure was reviewed. The procedure described the evaluation criteria. The procedure also described how to handle suppliers that did not meet the evaluation criteria. The supplier evaluation reports of the critical 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 ***Dean Superior Textile Co. Ltd*** located at ***Baota Industrial Park West Zone, Dean County Jiujiang City, Jiangxi Province China*** was considered to be operating at an acceptable level of compliance with the ISO 9001: 2015 Standard requirements.

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/