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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	10/10 Textile Joint Stock Company
Corporate address of manufacturer	9/253 Minh Khai street, Hai Ba Trung District, 114034 Hanoi, Vietnam
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	1. 10/10 Textile Joint Stock Company 9/253 Minh Khai street, Hai Ba Trung District, 114034 Hanoi, Vietnam 2. 10/10 Textile Joint Stock Company, Km24, Highway 5, Phan Boi, Di Su, My Hao commune, Hung Yen province, Vietnam 3. 10/10 Textile Joint Stock Company Vang village, Co Bi Commune, Gia Lam District, Hanoi, Vietnam
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	12-16 November 2018
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard
Introduction	
Brief summary of the manufacturing activities	10/10 Textile Joint Stock Company is a contract manufacturer for Vestergaard S.A. Three 10/10 Textile Joint Stock Company manufacturing sites were inspected with manufacturing activities indicated below: <u>10/10 Textile Joint Stock Company, 9/253 Minh Khai street, Hai Ba Trung district, 114034 Hanoi, Vietnam: (Minh Khai site)</u> Activities carried out at this site included warehousing of treated fabric and finished goods, cutting, sewing, stitching, labelling, baling, packaging and quality control testing of Long Lasting Insecticide treated nets (LLIN). Both physical and chemical quality control tests were performed at this site. The testing laboratory is Vestergaard Vector Control Laboratory. <u>10/10 Textile Joint Stock Company, Km24, Highway 5, Phan Boi, Di Su, My Hao commune, Hung Yen province, Vietnam: (Hoang Hop site)</u> Activities carried out at this site included warehousing of raw materials and knitted fabric, in-process checks and knitting.

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	10/10 Textile Joint Stock Company Vang village, Co Bi commune, Gia Lam District, Hanoi, Vietnam: (Co bi site) Activities carried out included the manufacture of Deltamethrin master batch, extrusion, processing of the fabric (coating), cutting, sewing stitching, labelling, packaging and quality control testing.
General information about the company and site	10/10 Textile Joint Stock Company; 9/253 Minh Khai street, Hai Ba Trung District, 114034 Hanoi, Vietnam: ISO 9001:2015 certification: Date of issue 19th January 2017, Expiry date 19th January 2020, Certificate number VN.3793229/Q. Issued by Bureau Veritas. Scope: Manufacture of netting fabric and mosquito bednet. In addition, the laboratory at this site was accredited - ISO/IEC 17025 certificate number Vilas 393 by the Ministry of Science and technology, Bureau of Accreditation. 10/10 Textile Joint Stock Company; Km24, Highway 5, Phan Boi, Di Su, My Hao commune, Hung Yen province, Vietnam and Vang village, Co Bi commune, Gia Lam District, Hanoi, Vietnam: ISO 9001:2015 certification: Date of issue 21st September 2018, Expiry date 19th January 2020, Certificate number VN.3793229/Q. Issued by Bureau Veritas. Scope: Manufacture of netting fabric and mosquito bednet.
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

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Exclusions and Non-applications of requirements in the QMS	Design and development were excluded from applications and requirements of the ISO 9001:2015 standard.
Out of scope	Products not submitted to WHO for prequalification
Restrictions	None
WHO products covered by the inspection	PermaNet® 2.0 (*Deltamethrin* 55 mg/m^2) 005-001 PermaNet® 3.0 (*side panel: Deltamethrin 80 mg/m^2; roof panel: Deltamethrin* 4 g/kg, *Piperonyl butoxide*-(PBO) - 25 g/kg) 005-002
Abbreviations	**Meaning**
LLIN	Long-lasting insecticide nets
MSDS	Material safety data sheet
PPE	Personal Protective Equipment
QA	Quality assurance
QC	Quality control
QMS	Quality management system
SOP	Standard operating procedure
PBO	Piperonyl butoxide

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

1. Organizational roles, responsibilities and authorities

The organizational roles and responsibilities were described in the quality manual. The organogram showed that the reporting lines of the Quality Control were independent of those for production management.

2. Quality policy and quality objectives

The quality policy and 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 during the induction training and was displayed on noticeboards.

3. Management review

An established procedure for management review was in place. Management reviews were conducted once a year. Management review was performed in accordance with the established procedure and met the requirements of the standard. The most recent management review minutes were reviewed. Quality Objectives were reviewed, and targets set for the following year.

4. Leadership

Leadership commitment with respect to the quality management system was demonstrated by ensuring that resources necessary for implementation of the quality management system were determined and provided, engaging, directing and supporting personnel in fulfilling their responsibilities and roles. The manufacturer monitored and measured the ability of the quality management system to meet planned results.

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5. Control of documented information

Control of documented information was managed centrally at the Minh Khai Site. Document control was described in the quality manual. It adequately described creation, approval, distribution and review documents. High level quality documents were retained for 2 years. Quality documents were retained for a period equivalent to the shelf life of the product plus a year.

6. Personnel competence and training

The relevant procedure for training was reviewed. Training was generated and planned from annual staff reviews, approved by management, arranged by Human Resource department. Training records were reviewed and found satisfactory.

7. Risks and opportunities

The relevant procedure for risk management was reviewed. It described the methods applied to risk management and the criteria applied by each department to identify risks. The risk register was still under development. The risk register described risks identified in each department along with mitigations and planned review dates.

8. Control of changes

Changes were controlled centrally from the Minh Khai Site. An established procedure for change control was in place. The facility maintained a change control register. Changes were reviewed.

9. Internal Audits

Internal audits were conducted in accordance with the relevant procedure. The internal audit schedule, and audit plan for 2018 were in place. The audit plan indicated areas to be audited, audit team members and ISO clauses covered. The internal audit report for 2018 was reviewed and found satisfactory.

10. Control of non-conforming products

The manufacturer had several measures in place for quality control and detection of nonconforming goods including, physical inspection of knitted fabric and sewn bed nets. Records on defects identified were maintained. A procedure for handling of non-conforming results in the laboratory number was in place. It allowed for investigations both in laboratory and production, resampling and retesting. Handling of non-conforming results in the laboratory was reviewed and found satisfactory.

11. Performance evaluation

The manufacturer monitored key processes and product quality parameters. The Acceptance, Testing and Inspection (ATI) records for the month of September 2018 were reviewed. The results for the 3 sites were evaluated and analyzed. The records reviewed showed that processes were within control limits.

12. Complaint handling and Customer satisfaction

Complaints were handled by Vestergaard S.A. Complaints were registered. Any actions with regards to complaints were documented. Complaints were reviewed and found satisfactory.

13. Design and development of products

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

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14. Support

Infrastructure and work environment

The infrastructure at the 3 sites was generally well maintained. The floors and external environments were clean and adequately maintained. MSDSs were available in the warehouses. The staff were provided with PPE.

Monitoring and measuring resources

Equipment qualification, calibration and maintenance records were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

15. Production and service provisions

Control of Production

10/10 Textile Joint Stock Company (Co Bi site)

The manufacture of *Deltamethrin* master batch involved mixing, extrusion, cooling, pelletizing and sieving and packaging. The mixing time was monitored. Quantities weighed, and batch numbers of the raw materials used for production were recorded. Processing temperatures were controlled, monitored and recorded. The master match was sampled for *Deltamethrin* content. The test for *Deltamethrin* content was performed at the Minh Khai site. Retention samples of the master batch were also maintained. At the time of the audit, the manufacture of *Deltamethrin* master batch was ongoing.

Only the roof of PermaNet® 3.0 bednet contained both *Deltamethrin* and PBO. The side of the net contained *Deltamethrin* only. PermaNet® 2.0 contained *Deltamethrin* only.

The manufacture of the roof of PermaNet® 3.0 involved blending of the master batch with other ingredients, extrusion, cooling, pre-setting, warping and knitting. Predetermined quantities of ingredients were blended and extruded at predetermined temperatures.

The manufacture of the side panels of PermaNet® 3.0 involved chemical treatment (coating) of the greige fabric, stentering, cutting.

Then PermaNet® 3.0 roof and side panel were stitched together, labelled, packed and baled.

The manufacture of PermaNet® 2.0 involved chemical treatment (coating) of the greige fabric, stentering, cutting, sewing, stitching, labelling, packaging and baling.

Cleaning records were available. In-process parameters were monitored. The temperatures of the drying chambers were monitored and controlled. The temperature indicators were calibrated.

Finished bed nets were sampled and sent to the Vestergaard laboratory at Minh Khai Site. The finished bed nets were released to the market following analysis at Minh Khai Site and review of production data by Quality Assurance Executive of Vestergaard. Traceability of the batch numbers to the active ingredients, laboratory results etc. was available.

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The laboratory carried out physico-chemical in-process tests on the bed nets. These included bursting strength, GSM, *Deltamethrin* content, PBO content, denier among others. A sample register was in place. Samples were adequately labelled and stored. The equipment in the laboratory was calibrated. Laboratory test results were adequately documented. The *Deltamethrin* content test results and raw data for several batches were reviewed and found satisfactory. All the issues raised related to control of production were addressed satisfactorily by the manufacturer.

10/10 Textile Joint Stock Company (Minh Khai site)

The fabric treated at the Co Bi site was transported to the Minh Khai site for further processing. The treated fabric was sampled and visually inspected for defects confirmed upon receipt. The quantities were confirmed on receipt of the treated fabric. Fabric inspection records were maintained. The fabric was stored at ambient temperatures.

The treated fabric was then cut, sewed, labelled, and baled and packaged according to customer specifications. Batch numbers of the product under manufacture were indicated at the different stages of production to ensure traceability. A calibrated tape measure was used to measure the length of the fabric to cut. The sewed fabric was inspected, and records maintained. The fabric was inspected for tears, holes, stains, sewing defects etc. At the time of the audit PermaNet® 2.0 was being manufactured.

The laboratory equipment was uniquely identified and calibrated. The test for denier was witnessed during the inspection. A sample register was in place. Samples were adequately labelled and stored. The equipment in the laboratory was calibrated. Laboratory test results were adequately documented. The *Deltamethrin* content test results and raw data for several batches were reviewed and found satisfactory. All the issues raised related to control of production were addressed satisfactorily by the manufacturer.

10/10 Textile Joint Stock Company (Hoang Hop site)

The incoming yarn was stored at ambient temperature. Stock cards were maintained. The incoming yarn was sampled and tested. Activities carried out at this site were mainly warping, knitting and in-process checks. Process parameters were monitored. The knitted fabric was inspected for defects and records maintained. The rolls of knitted fabric were stored in the warehouse.

The laboratory equipment was uniquely identified and calibrated. The laboratory only carried out tests for denier. Records of the test for the incoming yarn were reviewed and found satisfactory.

Identification and traceability

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability. All the issues raised related to identification and traceability were addressed satisfactorily by the manufacturer.

Release of products and services

Batch release followed review of production data and laboratory test results. Samples of the bed nets (finished products) were sent to the laboratory at the Minh Khai Site for analysis. Batch release was done by the Quality Assurance Executive of Vestergaard.

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16. Preservation

The raw materials were stored at ambient temperature. The containers of the raw materials were inspected for damages and quantities confirmed upon receipt. The manufacturer relied on Certificates of Analysis provided by the supplier. Stock cards were available.

17. Post-delivery Activities

Storage stability

One batch per order was subjected to stability studies. The batches were subjected to temperatures of 40±2ºC for 8 weeks for PermaNet® 2.0 and for the side of PermaNet® 3.0, and 54±2ºC for 2 weeks for the roof of PermaNet® 3.0. Results of the analysis for several batches of PermaNet® 2.0 were reviewed and found to comply with specifications.

18. Control of externally provided processes and products

Selection of suppliers was managed by Vestergaard. The procedure for control of suppliers described the criteria for selection of suppliers which involved audit of the supplier and performance review of the suppliers. The audit of the supplier was conducted using a questionnaire. Performance review of the suppliers was conducted annually. A list of critical suppliers was available. Performance reports of the suppliers were reviewed and found satisfactory.

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 ***10/10 Textile Joint Stock Company*** located at respectively:

a) ***9/253 Minh Khai street, Hai Ba Trung District, 114034 Hanoi, Vietnam***
b) ***Km24, Highway 5, Phan Boi, Di Su, My Hao commune, Hung Yen province, Vietnam***
c) ***Vang village, Co Bi Commune, Gia Lam District, Hanoi, Vietnam***

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.

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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/

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