



**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	Vestergaard Sàrl. Place Saint François 1 1003 Lausanne, Switzerland		
Inspected site			
Name & address of inspected manufacturing site(s)	10/10 Textile Joint Stock Company <u>Addresses:</u> <ul style="list-style-type: none"> • 198 Tran Phu Street, Phuc Yen, Vinh Phuc, Vietnam (Phuc Yen site) • Nguyen Van Linh Street, Di Su Ward, My Hao Town, Hung Yen, Vietnam: (Long Ha site) • 9/253 Minh Khai Street, Hai Ba Trung district, 114034 Hanoi, Vietnam: (Minh Khai site) • Km24, Highway 5, Phan Boi, Di Su, My Hao commune, Hung Yen province, Vietnam: (Hoang Hop site) • Vang village, Co Bi commune, Gia Lam district, Hanoi, Vietnam: (Co Bi site) 		
Unit/Block/Workshop	Not applicable.		
Inspection details			
Dates of inspection	20-24 June 2022		
Type of inspection	Re-inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.		
Introduction			
Brief description of the manufacturing activities	<p><u>Phuc Yen site</u> Activities performed by this site included warehousing, coating, cutting, sewing, labelling, baling, and packaging.</p> <p><u>Long Ha site</u> Activities performed at this site included heat setting of the polyethylene roof, impregnation of the polyester sides.</p> <p><u>Minh Khai site</u></p>		



	<p>The site acts as the Head office for the activities in Vietnam. Manufacturing activities performed at this site included warehousing of treated fabric and finished goods, cutting, sewing, labelling, baling, packaging, and quality control testing of Long-lasting Insecticide treated nets (LLIN). Both physical and chemical quality control tests were performed.</p> <p><u>Hoang Hop site</u> Activities performed at this site included warehousing, extrusion, warping, and knitting.</p> <p><u>Co Bi site</u> Activities performed included the manufacture of the master batch, extrusion, heat setting, coating, cutting, sewing, labelling, baling, and packaging.</p>
General information about the company and site	<p>10/10 Textile Joint Stock Company manufactured the Long Lasting Insecticide bed nets on contract for Vestergaard Sàrl. Vestergaard Sàrl is responsible for the release of the products to market.</p> <p>10/10 Textile Joint Stock Company was ISO 9001:2015 certified; ISO certificate number VN06633, issued by Bureau Veritas. Issued: 27-04-2022 Expires: 19-01-2023. Scope: “Manufacture of Mosquito Netting fabric and Mosquito bed net.”</p>
History	The facility was last inspected by WHO on 12 th – 16 th November 2018.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	<p>Document review including but not limited to:</p> <ul style="list-style-type: none"> • 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 <p>Physical areas:</p> <ul style="list-style-type: none"> • Raw material and finished goods • Production areas • Quality control laboratory



Exclusions and Non-applications of requirements in the QMS	Design and development of products and services was excluded from the QMS of the facility.
Out of scope	The manufacture of other products not submitted to the PQT programme were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	<ul style="list-style-type: none"> • PermaNet 2.0 (<i>Deltamethrin</i> 55 mg/m²) • PermaNet 3.0 (roof panel: <i>Deltamethrin</i> 4 g/kg, <i>Piperonyl butoxide</i> - (PBO)- 25 g/kg; side panels: <i>Deltamethrin</i> 84 mg/m²)
Abbreviations	Meaning
CoA	Certificate of Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
PBO	Piperonyl butoxide

Part 2	Brief summary of the findings and comments
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1. Organizational roles, responsibilities, and authorities

10/10 Textile Joint Stock Company, Vietnam acts as the Contract Acceptor to Vestergaard, Switzerland. A contract detailing the roles and responsibilities dated 01 April 2014 was available. Several suppliers were contracted by the company. Audit reports of the critical suppliers were available. Roles and responsibilities were defined, and authorities outlined.

2. Quality policy and quality objectives

An established quality policy and quality objectives were in place. The quality policy included both commitments to satisfy applicable requirements and make continuous improvement to enhance production, quality, minimize negative impacts on the environment and employees, health and maintain safe working conditions. Each workshop had defined quality targets to monitor and measure. The quality objectives and targets were discussed in the management review each year.

3. Management review

The procedure and minutes for the management review were reviewed. Management reviews were conducted once every year. The review included the status of actions from previous management review, customer satisfaction, implementation of the quality management system and trend evaluations, evaluation of the quality objectives, implementation of processes and conformity of products, changes to QMS, internal audits etc. Management review was performed in accordance with the established procedure and met the requirements of the standard.



4. Leadership

The manufacturer had an organogram in place. Production was headed by the Deputy Director of Production while quality assurance and quality control (in-process) were headed by the Deputy Director of Technology. The Deputy Director of Production and Deputy Director of Technology reported independently to the CEO. Top management communicated the importance of effective quality management and of conforming to the quality management system requirements through trainings. The quality policy and quality objectives were displayed in various areas throughout the different sites. The manufacturer also promoted improvement through internal audits, corrections and corrective actions and management reviews.

5. Control of documented information

Documents were managed centrally from the Minh Khai Site. The relevant document control procedure was reviewed. Documents were approved by the Director General. The procedure described the creation, identification, and approval of documents. Quality documents were retained for a period equivalent to the shelf life of the product plus one year. Documents of external origin were identified and controlled.

6. Personnel competence and training

The relevant procedure for training was reviewed. Training plans were created by the Human Resource department following requests from the other different departments. The training plans were approved by the General Director. The training plans for 2021 and 2022 were reviewed. The training topics included safety in production, First Aid, Trainings on skills for staff in cutting, sewing, knitting, coating etc. Trainings were evaluated and records maintained.

7. Risks Management

The procedure for Risk Management was in place. The procedure described the identification, evaluation, and prioritization of risks. The prioritization of the risks was based on the probability, impact, and detectability of the risk. Risks were evaluated yearly. A risk register was also in place. Risk identification and evaluation covered the full product cycle and was performed for each of the sites. This was found satisfactory.

8. Control of changes

The Change Control procedure was discussed. The procedure made provision for the appointment of an appropriate change control Team consisting of at least QC and Production representation. An appropriate change control form drives the activity. Process validation if required supports the change process. Validation Report for the roof – heat setting process at new workshop was inspected. The validation process was made and completed within the third quarter of 2020.

9. Internal Audits

Documented information on internal audits was available. The audit report for the audit conducted on 23 March 2022 was reviewed. Internal audits were planned for newly added site; Phuc Yen - September 2022. An appropriate yearly audit plan was available. Training records of the auditors were verified and found compliant.



10. Control of nonconforming products

The manufacturer had in place instructions for handling of defective nets after inspection, the procedure for corrective and preventive actions and working instructions for Acceptable Quality Level. These described the actions and steps to take when handling defects and nonconforming fabric and bed nets. A number of quality control measures were in place to control nonconforming products. These included visual inspection of knitted fabric and sewn bed nets, in-process control tests for determination of amount of deltamethrin coated onto the fabric, GSM, denier etc. Records on defects were maintained.

11. Complaints and customer satisfaction

Customer satisfaction surveys were conducted yearly. The customer satisfaction survey report for the year 2020 was reviewed. The survey covered a range of aspects that generally assessed whether the quantities were produced, sampled, and delivered as per the contract. Market complaints were managed by Vestergaard Sàrl, Switzerland. The complaint would then be communicated to 10/10 Textile Joint Stock Co. Ltd for investigation. The manufacturer maintained a complaint register.

12. Performance evaluation

Product Performance evaluation was done monthly. Performance evaluation was performed by monitoring and trending the process capability of key process and product attributes such as Deltamethrin content, PBO content, GSM, bursting strength (netting), bursting strength (seam), R-isomer, mesh count etc. All the parameters were under control. These evaluations were discussed in the management review.

13. Design and development of products

Design and development of products and services was excluded from the requirements of the quality management system.

14. Support

Infrastructure and work environment

The infrastructure was generally well maintained. Rodent traps had been installed at the different sites. Personnel were appropriately dressed depending on their area of work. Personnel were gowned in overalls, shoes, ear plugs etc.

Monitoring and measuring resources

A calibration and maintenance schedule was in place. Equipment were identified and calibration statuses indicated. Calibration certificates for the storage stability chambers and HPLC were reviewed. The qualification records for HPLC were also reviewed. The tests performed included flow rate, accuracy of injection, repeatability of injection, linearity of the injection, detector, column temperature etc. The calibration certificates of the weighing balances were also in place.



15. Production and service provisions and Preservation

Control of Production

Minh Khai Site

The impregnated fabric was received along with an internal transportation document which provided information on site where the impregnated fabric was from, batch number, fabric length, roll number, quantity etc. The quantities were verified on receipt. All the fabric (100%) was inspected for defects such as holes, stains, width etc. Instructions for fabric checks were reviewed. A report on nonconforming fabric was maintained.

The inspected fabric was cut, sewed, labelled, and packaged according to customer requirements. The procedure for cutting, sewing, and packaging was in place. A report on results of visual inspection of the cut fabric was also maintained. The measuring tapes were identified and calibrated. The sewed bed nets were inspected for defects such as open seams, holes, etc. Workmanship and appearance record was in place. The procedure for handling of defective nets after inspection was reviewed. Access to the labels was controlled. The labels were under lock and key. Records on label issuance and accessories were retained. The in-process tests included GSM, number of holes per square meter etc. For every order an acceptance testing inspection was performed. This was done following the working instructions for AQL.

Inventory in the warehouse was managed by use of stock cards. The status of the materials in the warehouse were indicated and found satisfactory.

The laboratory carried out both physical and chemical testing of the finished bed nets. A sample register was in place. Samples were adequately labelled and appropriately stored. Test reports for the bursting strength, Wash resistance index, determination of deltamethrin and PBO content were reviewed. The analytical method validation report for the determination of Deltamethrin and PBO in the roof of PermaNet 3.0 was reviewed. The certificates of analysis for the reference standards were available. The reference standard for PBO was kept in the fridge at 2-8°C as per the label instructions.

Batch release was carried out centrally at the Minh Khai site following review of production data and laboratory test results by the Quality Assurance Executive.

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

One batch per order was subjected to accelerated stability studies. The batches were subjected to temperatures of 54±2°C for 4 weeks and 40±2°C for 8 weeks. Results of the analysis for several batches were reviewed and found to comply with specifications.



Co Bi site

Inventory in the warehouse was managed by use of stock cards. The status of the materials in the warehouse were indicated and found satisfactory. The names and batch numbers of the materials were indicated on the stock cards. Materials were received along with Certificates of Analysis from approved vendors. The quantity and physical condition of the containers were verified at receipt.

The manufacture of Deltamethrin master batch involved mixing of the Deltamethrin Technical grade with other ingredients, extrusion, cooling, pelletizing and post-mixing and packaging. Line clearance was performed before production. A checklist to verify that the correct materials have been issued to production was in place. The manufacturing recipe was in place. The quantities of the raw materials weighed were verified. The names and batch numbers of the raw materials were recorded. The mixing time was monitored. The temperatures of the extruder and water baths were monitored and recorded. The deltamethrin master batch was sampled and deltamethrin content in the master batch determined at Minh Khai. The master batch was used for production following receipt of test results. A sample of the master batch was also retained.

The manufacture of the roof of PermaNet 3.0 involved mixing of master batch, PBO, color and other ingredients. The quantities added to the mixture were controlled by an automatic dosing system. This was followed by extrusion, warping, and knitting. The temperatures at which extrusion was performed were monitored. Process records such as the warping record, knitting record etc. were in place. The knitted fabric was inspected for defects and records were maintained.

The manufacture of PermaNet 2.0 involved impregnation of the fabric, heat setting, cutting, sewing, labelling, and packaging. The coating solution was prepared by mixing of deltamethrin with water and other ingredients. The mixing tanks were graduated. Cleaning records were maintained. The mixing times were monitored, and records retained. The in-process parameters included the monitored of in-process parameters included, bursting strength, GSM etc. The temperature zones on the extruders were appropriately identified. The temperatures of the drying chambers were monitored and controlled.

Hoang Hop site

Inventory was managed by use of stock cards. The batch number of the incoming yarn was indicated on the stock cards. The incoming yarn was sampled and tested for denier, tenacity, and elongation. Activities carried out at this site were mainly extrusion, warping and knitting. The master batch was used for production following receipt of test results from Minh Khai. The temperatures of the extruder and water baths were monitored and recorded in the process parameter record. The in-process checks included tenacity, denier, and GSM etc. Test records were maintained. The procedures for performing Tenacity and denier were reviewed.

Long Ha

At the time of the inspection heat setting of the polyethylene fabric (roof of PermaNet 3.0) was ongoing. In-process controls included GSM and the number of holes per square inch. There was also provision for impregnation of polyester fabric. However, these were not operational. The temperatures of the stenters were monitored and recorded in the stenter process parameter log.



Phuc Yen site

The site is one of the newly added manufacturers to the stables of 10/10 and a first inspection by WHO. The activities at the site appeared well controlled with appropriate QA oversight by 10/10. The site was ISO certified on April 2022 with manufacturing activities limited to LLIN production. Bin cards were used for stock monitoring. In process quality controls were conducted at specified intervals.

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

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

Contracts between 10/10 Textile Joint stock company and suppliers of raw materials were in place. The roles and responsibilities were defined. List of the approved suppliers was in place. Supplier Performance evaluation reports of several suppliers were reviewed. Supplier performance evaluation took into consideration the following among others: supplier capacity, speed of response to queries, supplier communication, capacity to improve, supplier compliance with Vestergaard supply chain requirements, resolution of complaints and sustainable improvements among others.

Part 3	Conclusion – Inspection outcome
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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

- *198 Tran Phu Street, Phuc Yen, Vinh Phuc, Vietnam (Phuc Yen site)*
- *Nguyen Van Linh Street, Di Su Ward, My Hao Town, Hung Yen, Vietnam: (Long Ha site)*
- *9/253 Minh Khai Street, Hai Ba Trung district, 114034 Hanoi, Vietnam: (Minh Khai site)*
- *Km24, Highway 5, Phan Boi, Di Su, My Hao commune, Hung Yen province, Vietnam: (Hoang Hop site)*
- *Vang village, Co Bi commune, Gia Lam district, Hanoi, Vietnam: (Co Bi site)*

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/>