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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	10/10 Textile Joint Stock Company
Corporate address of manufacturer	Vestergaard Sarl. Place Saint François 1 1003 Lausanne, Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	The following subsidiaries of 10/10 Textile Joint Stock Company were inspected: • 10/10 Textile Joint Stock Company (Co Bi Factory): Vang village, Co Bi commune, Gia Lam district, Hanoi, Vietnam. • 10/10 Textile Joint Stock Company (Trading Phu Lan Factory): Phong Coc Residential Group, Minh Duc Ward, My Hao Town, Hung Yen Province • 10/10 Textile Joint Stock Company (Huu Nghi Factory): Minh Duc Industrial Park, 1228 Nguyen Van Linh, Minh Duc Ward, My Hao Town, Hung Yen Province • 10/10 Textile Joint Stock Company (Phuc Yen Factory No 5 Business Location): Nhat Chieu Hamlet, Lien Chau Commune, Yen Lac District, Vinh Phuc Province • 10/10 Textile Joint Stock Company (Phu Lan Factory): Van Hoi Village, Dai Thang Commune, Phu Xuyen District, Hanoi • 10/10 Textile Joint Stock Company (Minh Khai Factory – Quality Control Laboratory): 9/253 Minh Khai Street, Vinh Tuy Ward, Hai Ba Trung District, Hanoi
Unit/Block/ Workshop	See above.
Inspection details	
Dates of inspection	8 - 12 July 2024
Type of inspection	Initial 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	10/10 Textile Joint Stock Company (Co Bi Factory): Vang village, Co Bi commune, Gia Lam district, Hanoi, Vietnam The activities inspected at this site included the storage of the raw materials and formulation (PermaNet Dual). 10/10 Textile Joint Stock Company (Trading Phu Lan Factory): Phong Coc Residential Group, Minh Duc Ward, My Hao Town, Hung Yen Province The activities carried out at this facility included preparation of the coating solution and impregnation of fabric. 10/10 Textile Joint Stock Company (Huu Nghi Factory): Minh Duc Industrial Park, 1228 Nguyen Van Linh, Minh Duc Ward, My Hao Town, Hung Yen Province The activities carried out at this facility included preparation of the coating solution and impregnation of fabric. 10/10 Textile Joint Stock Company (Phuc Yen Factory No 5 Business Location): Nhat Chieu Hamlet, Lien Chau Commune, Yen Lac District, Vinh Phuc Province The activities carried out at this facility included cutting and sewing. 10/10 Textile Joint Stock Company (Phu Lan Factory): Van Hoi Village, Dai Thang Commune, Phu Xuyen District, Hanoi This site carried out the heat setting of the net fabric. 10/10 Textile Joint Stock Company (Minh Khai Factory – Quality Control Laboratory): 9/253 Minh Khai Street, Vinh Tuy Ward, Hai Ba Trung District, Hanoi Only the quality control activities were inspected.
General information about the company and site	Scope: ‘‘Manufacturing of Mosquito Netting fabric and mosquito bed nets’’ Certificate Number: VN010050 Valid from: 09/01/2023 Valid until: 19/01/2026 All the 10/10 subsidiary manufacturing sites were ISO 9001 certified. The certificate was issued by Bureau Veritas Certification.

History	This was the first WHO inspection of the 10/10 Textile Joint Stock Company subsidiary manufacturing sites (indicated above) except for the Quality Control laboratory at Minh Khai Factory and the Co Bi factory. The Co Bi and Mihn Khai factories were last inspected by WHO in June 2022.
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 and services was excluded from the QMS of the facility.
Out of scope	The manufacture of other products not submitted to PQ was not included in the scope of this inspection. At the Minh Khai Factory, activities related to warehousing of treated fabric and finished goods, cutting, sewing, labeling, baling, and packaging were not inspected, as these activities were already inspected by WHO in June 2022. Additionally, at Co Bi Factory, activities related to the manufacture of the master batch, extrusion, knitting, coating, cutting, sewing, labeling, and packaging (for PermaNet 2.0 and PermaNet 3.0) were not inspected during this inspection. These activities were already inspected by WHO in June 2022.
Restrictions	None

WHO products covered by the inspection	• PermaNet 2.0 (Deltamethrin 55 mg/m2) - 005-001 • PermaNet 3.0 (roof panel: Deltamethrin 4.0 g/kg, Piperonyl butoxide (PBO) 25.0 g/kg; side panel: Deltamethrin 84 mg/m2) - 005-002 • PermaNet Dual (Deltamethrin 2.1 g/kg, Chlorfenapyr 5.0 g/kg) - P-03228
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 quality objectives were approved by top management. The 2024 quality objectives were related to satisfying customer requirements, safety, nonconformities, and complaints. The quality policy was appropriate to the purpose and context of the organization. Top management demonstrated leadership and commitment with respect to the quality management system by promoting improvement through audits, corrections, and corrective actions. It also supported management roles by providing resources and training.

2. Management review

The procedure for management review was checked. The management review meetings were held once a year. Management review meetings could also be conducted to address any issues that may arise. The agenda included: status of actions from previous meetings, changes, information on implementation and effectiveness of the integrated quality management system, nonconformities, and corrective actions, monitoring and measurement results, risk and opportunities, resources, performance of external suppliers, etc. The General Director of 10/10 Textile Joint Stock Company chaired the meeting. The most recent management review minutes were reviewed.

Vestergaard also held periodic quality management reviews with 10/10 Textile Joint Stock Company. The minutes of the latest Quality Management review were also reviewed. The agenda included the following:

- Results of the quality audits
- Status in achieving QMS and quality objectives
- Process capability of key manufacturing processes
- Summary of customer feedback and complaints
- Opportunities for improvement
- New objectives (QMS and product quality for 2024)

The meeting was attended by top management from both 10/10 Textile Joint Stock Company and representatives from Vestergaard. There were no complaints from customer complaints registered in 2023. There were no complaints from Vestergaard to 10/10 Textile Joint Stock Company. The key quality attributes monitored and analyzed for PermaNet Dual included ‘‘Formulation preparation first rejection rate’’, chemical content etc. Opportunities for improvement were also documented.

3. Organizational roles, responsibilities, and authorities

Signed and dated organizational structures were in place. Vestergaard oversaw the manufacturing activities at 10/10 Textile Joint Stock Company. Vestergaard and 10/10 Textile Joint Stock Company had separate organograms. The hierarchical structure and reporting lines were defined. The roles and responsibilities of the key staff and departments were described in the quality manual. The responsibilities of the workshop managers, QA manager and laboratory manager were reviewed.

4. Document control

The procedure for control of documented information was reviewed. The procedure described the creation, identification, review, approval, issuance, retention, and destruction of documents. The procedure also described the different types of documents and their respective durations for review. A document distribution list was available. The retention period for the different types of documents was also defined. The duration of document retention was dependent on the type of document. Production records were retained for 5 years. Documents were retained both as hard copies and as soft copies by QA department.

5. Personnel competence and training

The procedure for training of quality control lab staff – ‘‘Acquisition for training and assessment of Quality Control Laboratory (QCL) employee competence’’ was reviewed. The procedure specified who conducts trainings, how they should be conducted, how frequently they should be conducted, and maintenance of evidence of trainings.

The training plan for QCL staff for 2023/2024 was in place. The training plan provided details on the training topics for all the laboratory staff. The laboratory had a total number of 18 staff. Training records of the new staff on textile testing were reviewed. The effectiveness of trainings was assessed, and records maintained.

6. Risk Management

The procedure for risk assessment and opportunity management was reviewed. The procedure described the identification and control of risks and opportunities. The procedure applied to all departments, workshops, and units (processing and business) of 10/10 Textile Joint Stock Company. Risk assessment was conducted once annually. The criteria for the evaluation of risks were described. The Risk priority number (RPN) involving failure mode's severity, probability of occurrence, and likelihood of detection on a defined numeric scale were described. The risks were categorized into levels 1, 2 and 3 depending on the RPN.

The risk assessment for Huu Nghi Factory was reviewed. The risk assessment covered the following aspects: material receipt, mixing, preparation of the fabric for the coating process, storage, machinery, analysis etc.

7. Internal Audits

The established procedure for internal audits was reviewed. The procedure described the planning, preparation, conduct, reporting and closing of audits. The procedure applied to all departments of the company. The audits were categorized into planned and unplanned audits. The internal auditors were trained on the requirements of ISO 9001, ISO 14001, ISO 45001, and company procedures. Training records of the internal auditors were retained. The internal auditors did not audit their areas of work.

The latest internal audit report for the Phuc Yen site, the list of participants and internal audit notice were in place. Internal audits were conducted using a check list. The nonconformities raised were documented, investigated, corrections and corrective actions implemented. A follow-up to assess the effectiveness of the corrections and corrective action had also been completed and documented.

8. Complaints

The procedure for handling customer claims and product recalls was in place. The procedure applied to both internal and external customers. Supplier and material availability complaints were excluded from the scope of this procedure. The template of the customer complaint record was in place. There were no complaints from customer registered in 2023. A quality complaint registered in 2019 was reviewed.

9. Customer Satisfaction

The procedure for handling customer satisfaction and feedback was reviewed. The procedure described how the customer satisfaction surveys were to be conducted and the evaluation of the feedback. A 2023 customer satisfaction survey was provided. The survey sought customers perceptions on timely delivery, packaging, quality of the product, cost, etc. Evidence of the implementation of the procedure was available, assessed, and found adequate. The survey was conducted using a questionnaire. The customer survey report was retained for 5 years.

10. Change Control

Vestergaard was responsible for the approval of any changes including product and process specifications. The procedure for change management was in place. Changes were initiated using a change request form. Major changes were those considered to impact:

- Product performance,
- Process performance and
- Labor, health, and safety

Changes were reviewed and documented on the change order form. Changes were registered in the change masterlist. A change review committee was selected depending on the type and nature of the change. The change review committee was selected by the change coordinator. A list of changes was provided and selected changes reviewed by the inspection team.

11. Performance Evaluation

The process parameters monitored and analyzed for PermaNet 2.0 included: Deltamethrin content, weight, mesh count, bursting strength - seam, width, length, wash resistance index, dimension stability after washing, workmanship, and appearance.

The parameters for PermaNet 3.0 monitored and analyzed included: Deltamethrin content, PBO content, weight, mesh count, busting strength, Deltamethrin retention after storage, PBO retention after storage, width, length, dimension stability, Deltamethrin and PBO contents after wash resistance index, workmanship, and appearance.

The parameters monitored for PermaNet Dual included: Deltamethrin content, Chlorfenapyr content, weight, mesh count, bursting strength, bursting strength seam / bursting strength netting, Deltamethrin retention after storage, storage stability at 40ºC, Chlorfenapyr retention after storage stability 40ºC, Deltamethrin and Chlorfenapyr contents after wash resistance index, workmanship, and appearance.

The performance evaluation reports detailing the analysis and evaluation of the above parameters were discussed in management review meetings.

12. Design and development of products

Design and development of products and services was excluded from the QMS of the facility.

13. Support

Infrastructure and work environment

The infrastructure at all the subsidiaries was well maintained. The personnel were appropriately dressed in personal protective gear. The facilities were equipped with fire extinguishers, spill kits, and eye washes. Material safety data sheets were in place.

Monitoring and measuring resources.

The 2024 calibration schedule for the lab equipment and balances was in place. The calibration records of the selected balances, rulers, HPLCs were reviewed.

14. Production and service provisions

Control of Production

The inspected activities for the manufacture of the Deltamethrin and Chlorfenapyr water dispersion preparations included premixing, mixing, and postmixing. The instructions for mixing were reviewed. The mixing times were monitored. This was then followed by the preparation of the coating solution, heat setting, impregnation, cutting, sewing, and packaging. Recipes for the preparation of the Deltamethrin and Chlorfenapyr water dispersion preparations and coating solutions were in place. Instructions for making the dye were also reviewed.

The greige fabric was inspected for defects prior to dyeing and records maintained. The instructions for PermaNet Dual impregnation and mixing records were in place. The temperatures of the chambers of the different stenters were monitored and recorded in the process parameter log. The in-process parameters included bursting strength, GSM etc. In-process test records were maintained.

Reports of visual inspection of the cut and sewn fabric were also maintained. The measuring tapes were identified and calibrated. The sewn bed nets were inspected for defects such as open seams, holes, etc. Display charts with guidance of net defects were in place. Access to the labels was controlled. The labels were under lock and key. The in-process tests included GSM, number of holes per square meter etc.

Selected batch records for PermaNet 3.0, PermaNet Dual and PermaNet 2.0 were reviewed.

The batches were released by Vestergaard QA following review of in-process and quality control lab test results.

Quality control laboratory

The laboratory carried out both physical and chemical testing of the finished bed nets. The physical tests performed included GSM, mesh count, bursting strength etc. A sample register was in place. The procedure for receipt and storage of samples was reviewed. Samples were adequately labelled and appropriately stored. The standard testing procedures for determination of Deltamethrin and Chlorfenapyr in water dispersion preparations respectively were reviewed.

The analytical validation report for determination of Deltamethrin and Chlorfenapyr in PermaNet Dual was reviewed. The validation parameters included: accuracy, linearity, specificity etc. The Limits of Detection (LOD) and Limits of Quantitation (LOQ) had been determined.

The standard testing procedure for determination of Deltamethrin and Chlorfenapyr in polyester PermaNet Dual was reviewed. Raw data and test reports for selected batches of PermaNet Dual, PermaNet 3.0 and PermaNet 2.0 were verified. The Certificates of Analysis (CoA) for primary standards of Deltamethrin and PBO and Chlofenapyr were checked.

Process validation

The process validation protocols and reports for Deltamethrin water dispersion and Chlorfenapyr water dispersion' were in place. The mixing process parameters for the following were defined: speed, temperature of the product, pressure, pump speed, and chiller temperature. The product specifications/requirements included: Deltamethrin and Chlorfenapyr particle size distributions, Deltamethrin and Chlorfenapyr contents, RSD of Deltamethrin and Chlorfenapyr contents, water dispersion stability etc. It was concluded that the mixing process met both the process and product performance criteria and was thus validated for mass production.

Waste management

Waste was disposed at a central location and then collected by a third party for destruction. The contract between 10/10 Textile Joint Stock Company and the third-party company was in place. A confirmatory declaration for the destruction of waste submitted to 10/10 Textile Joint Stock Company dated 10/01/2024 was also reviewed.

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

15. Preservation

The raw materials warehouse was at the Co Bi factory. The warehouse housed both active and inactive raw materials. Inventory records were managed by use of stock cards. The procedure for chemical management in the warehouse was reviewed. The procedure described the receipt, storage, and identification of materials. The following were verified upon receipt of raw materials at the house: physical condition of the containers, name, batch number expiry date etc. Quality issues encountered at receipt were documented on the quality report and sent to the Quality Assurance Manager.

16. Retention samples

A sample of every batch was retained. Retention samples were stored at ambient temperatures. Retention samples were retained for a period equivalent to the shelf life of the product plus a year. Inventory of the retention samples was controlled using stock cards.

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

The selection and evaluation of suppliers of the active ingredient was controlled by Vestergaard. The raw materials were supplied to 10/10 Textile Joint Stock Company by Vestergaard. The procedure for approval of potential suppliers was reviewed.

The suppliers of key materials were subjected to factory visits. The supplier assessment reports for selected critical suppliers were reviewed.

The procedure for evaluation of suppliers was also reviewed. The evaluation of suppliers was conducted once annually. The criteria for revaluation of suppliers were defined. The criteria included: price, cooperation on cost breakdown, on time/ in full deliveries, response to changing production and delivery plans etc. The 2023 supplier performance evaluation reports were also 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 subsidiaries of 10/10 Textile Joint Stock Company located at

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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/