

**Prequalification Team Inspection services  
WHO PUBLIC INSPECTION REPORT  
(WHOPIR)  
Vector Control Product Manufacturer**

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| <b>Part 1</b>                                                                        | <b>General information</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Manufacturers details</b>                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Name of manufacturer                                                                 | Net Health Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Corporate address of manufacturer                                                    | Plot No. 698, Net World Area, Dodoma Road, Kisongo Arusha, Tanzania                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Inspected site</b>                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Name & address of inspected manufacturing site(s) if different from that given above | As above<br><i>Note: Only one of the two manufacturing sites located at this address was covered during this inspection. The second manufacturing area belonging to another company, i.e. A to Z Textile Mills Limited, was inspected separately and is not covered in this report.</i>                                                                                                                                                                                                                                                                                   |
| Unit/Block/Workshop                                                                  | Not applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Inspection details</b>                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dates of inspection                                                                  | 18-19 June 2018.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Type of inspection                                                                   | Initial inspection.<br><br>The criteria for the inspection was the ISO 9001:2015 standard.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Introduction</b>                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Brief description of the manufacturing activities                                    | Net Health Limited is involved in the manufacture of long lasting insecticide treated nets (LLINs) and other products.<br><br>The activities related to manufacture of LLINs at the site included storage of raw materials and finished products, production of the treated fabric and quality control testing. After knitting, the knitted fabric was transported to A to Z Textile Mills Limited located at Plot No. 156-160, Unga Ltd– Industrial Arusha, where further processing of the fabric was carried out i.e. cutting, sewing, stitching, labeling and baling. |
| General information about the company and site                                       | Net Health Limited is a private manufacturing company involved in the manufacture of a wide range of products including LLINs.<br>The manufacturing facility was licensed by the Ministry of Industry, Trade and Investment, Government of Tanzania. The facility is also certified to ISO 9001:2015 with license number IND 17.4668 U/Q.<br><br>The quality management system i.e. policies, procedures, processes and leadership were similar to that of the company A to Z Textile Mills Limited.                                                                      |

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| History                                                                         | This was the first WHO audit of the site                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Brief report of inspection activities undertaken – Scope and limitations</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Areas inspected                                                                 | <b>Document review including but not limited to:</b> <ul style="list-style-type: none"> <li>• Quality Manual</li> <li>• Training</li> <li>• Risk management</li> <li>• Management review</li> <li>• Job descriptions and responsibilities of key personnel</li> <li>• Complaints</li> <li>• Non-conforming products</li> <li>• Data integrity</li> <li>• Product release</li> <li>• Batch processing records</li> <li>• Sampling and laboratory test reports</li> <li>• Control of changes</li> <li>• Internal audits</li> <li>• Calibration and equipment maintenance</li> </ul><br><b>Site areas visited:</b> <ul style="list-style-type: none"> <li>• LLIN production areas</li> <li>• Quality control laboratory</li> <li>• Raw material and finished goods warehouses</li> </ul> |
| Exclusions and Non-applications of requirements in the QMS                      | ISO 9001:2015 Clause 8.3 Design and Development for products and services                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Out of scope                                                                    | Products not submitted to WHO for prequalification.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Restrictions                                                                    | None.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| WHO products covered by the inspection                                          | <ul style="list-style-type: none"> <li>• MiraNet® (Alpha-cypermethrin 0.45%) 009-001</li> <li>• Olyset® (Permethrin 2%) 009-002</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Abbreviations</b>                                                            | <b>Meaning</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| MSDS                                                                            | Material safety data sheet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| PPE                                                                             | Personal Protective Equipment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| QC                                                                              | Quality control                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| QMS                                                                             | Quality management system                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

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| <b>Part 2</b> | <b>Summary of the findings and comments</b> |
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### 1. Organizational roles, responsibilities and authorities

The manufacturer had documented the organizational structure and defined designated responsibilities and authorities for key personnel. Reporting lines for quality and production were independent of each other.

## **2. Quality policy and quality objectives**

Top management had established an adequate quality policy with commitments to satisfy applicable requirements and continual improvement. The quality policy was appropriate to the purpose of the organization and had been communicated within the facility.

Quality objectives were documented, consistent with the quality policy and measurable.

## **3. Management review**

Management review was adequately described in the Quality Manual and reflected the inputs and outputs required by the standard. The management review was held at least twice a year.

Management reviews were considered acceptable at the closure of this inspection.

## **4. Leadership**

Top management was committed to the effective implementation of the QMS. Resources necessary for implementation of the QMS were determined and provided. The manufacturer monitored and measured the ability of the quality management system to meet planned results. Top management engaged, directed and supported personnel in fulfilling their responsibilities and roles.

## **5. Control of documented information**

Documented information was available both electronically and in hard copy. The procedure for control of documented information adequately described the control of documents. Hard copies were issued to heads of department and sections. These hard copies were controlled by use of copy numbers. Non-conformance raised in relation to this section have been addressed and the same shall be verified during future audits.

## **6. Personnel competence and training**

The manufacturer had an established procure for training. Training needs were identified by the training committee. The training programs for the year 2018 were reviewed. Training programs included leadership, quality awareness etc. Most of the trainings were in-house. Training records were reviewed. The effectiveness of the trainings was assessed.

## **7. Risks and opportunities**

The relevant established procedure was in place. The procedure was implemented as required by the standard. A risk register covering all aspects of production had been generated.

## **8. Control of changes**

The quality manual and procedures established described the process of change control adequately. No changes had been registered. The QMS had been completely updated and initiated in April 2017 to meet the requirements of ISO 9001:2015. From this time there have been no change control records generated. The third-party inspection report was reviewed to determine if this had covered the changes of the QMS to the new requirements. This showed that audit objective 2 was to “confirm the organization has effectively implemented its planned changes”. The third-party report stated that the planning was appropriate and the changes to the system were managed in accordance with the previous procedures.

## **9. Internal Audits**

The manufacturer had an established procedure on internal audits. Internal audits were planned, and an internal audit program implemented. Internal audits were conducted biannually for each department by qualified internal auditors. Internal audit schedule for the year 2018 and 2017 were reviewed. Internal audit reports were available. Audit results were communicated to top management and were reviewed during management review meetings.

## **10. Control of non-conforming products**

The relevant procedure was reviewed. Records were available, and these showed that the requirements of the procedure were being implemented.

## **11. Performance evaluation**

The manufacturer monitored and analysed key processes and product quality parameters such as denier, temperature content of active ingredient, bursting strength. This data was compiled on a weekly basis and analysed. The reviewed results indicated that the processes were within control. Non-conformances raised in relation to this section have been addressed and the same shall be verified during future audits.

## **12. Complaint handling**

Complaints were handled according to a documented procedure. Customer feedback was actively sought by use of questionnaires. A complaint register was available. At the time of the audit no customer complaint related LLINs had been registered.

## **13. Design and development of products**

Design and development were excluded from requirements of the Quality Management System of the facility.

## **14. Support**

### **Infrastructure and work environment**

The facility was generally well maintained. The work environment was found adequate with personnel wearing PPE. MSDS were available in warehouse.

### **Monitoring and measuring resources**

The documented procedure for preventive maintenance, preventive maintenance schedule and records were available. Calibration records for selected balances were reviewed. Equipment calibration status was displayed.

## **15. Production and service provisions**

### **Control of Production**

The manufacturing of Olyset® fabric involved blending of *permethrin* master batch with HDPE followed by heating, extrusion, cooling, pre-setting, warping and knitting. The manufacture of LLINs was performed according to documented production instructions. Production records were maintained indicating that processing temperatures were monitored. In process tests were performed throughout the manufacturing process and results documented. Completed batch manufacturing and testing records for the product MiraNet® LLIN were reviewed.

The knitted fabric was transported to A to Z Textile Mills Limited located at Plot No. 156-160, Unga Ltd– Industrial Arusha, where further processing of the fabric was carried out i.e. cutting, sewing, stitching, labelling and baling.

The QC function was independent of the other departments and was shared with the company A to Z Textile Ltd. The equipment in the laboratory were identified and calibrated. Sampling was carried out as per the established procedures and a sample receipt register maintained. Non-conformances raised in relation to this section have been addressed and the same shall be verified during future audits.

### **Identification and traceability**

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability. This area was considered acceptable at the closure of the inspection.

### **16. Preservation**

Retention samples were stored under ambient conditions. Non-conformances raised in relation to this section have been addressed and the same shall be verified during future audits.

### **17. Post-delivery Activities**

#### **Storage Stability:**

Storage stability studies were covered during the inspection of A to Z Textile Mill Ltd. Please refer to the WHOPIR for A to Z Textile Mill Ltd.

### **18. Control of externally provided processes, products and services**

The manufacturer had an established procedure for selection of suppliers. There was an established criterion for evaluation of external providers. The evaluation report for suppliers was available. Evaluation of suppliers was conducted every two years.

| <b>Part 3</b> | <b>Conclusion – Inspection outcome</b> |
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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 **Net Health Limited** located at **Plot No. 698, Net World Area, Dodoma Road, Kisongo Arusha, Tanzania** 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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| <b>Part 4</b> | <b>List of Standards and Guidelines referenced in the inspection report</b> |
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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, GHTEF/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/>