World Health Organization

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In reply please refer to: V2-447-3/ML/DS/1

Your reference: 028-003, SA2019-007
PPQC2019-013
PPQC2019-014
PPQC2019-022

NRS Moon netting FZE
Mr Rune Bosselmann
P.O Box 261218
Jebel Ali Free Zone
Dubai
Emirats arabes unis

09 October 2020

Dear Mr Bosselmann,

WHO Prequalification Unit (PQT) – Vector Control Product Assessment Team (VCP)
Letter of Prequalification

Product number: 028-003

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- **Tsara Soft – PQ Reference Number 028-003**

has been completed and it has been found to meet the norms and standards recommended by the World Health Organization (WHO) for long lasting insecticide treated net products and is acceptable, in principle, for procurement by the United Nations (UN) and other international agencies and countries.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of ISO 9001 Certification at the facilities used for the manufacture of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, the status of prequalification for this product will be changed from "Suspended" to "Prequalified" on the list of vector control products, which are considered to be acceptable, in principle, for procurement by UN and other international agencies and countries. This list is published by WHO at http://www.who.int/pq-vector-control/prequalified-lists/en/.

As identified in the WHO Decision Document NRS Moon Netting FZE, will be responsible for submitting quarterly reports for a period of two years to WHO PQT-VCP confirming the adherence to the declared formulation and manufacturing process at all manufacturing sites. These quarterly reports must contain the following:

- Affirmation that the manufacturing of products has been conducted in accordance with the declared product formulation and manufacturing process.
- List of production batches including the batch ID and production date.
- Supporting QA/QC reports verifying post-production compliance with the established specification.

The quarterly reports must be submitted on or before the following dates:

- 31 December 2020
- 31 March 2021
- 30 June 2021
- 30 September 2021
- 31 December 2021
- 31 March 2022
- 30 June 2022
- 30 September 2022
- 31 December 2022

WHO PQT may extend this period for required reporting based on the review of submitted reports and/or complaints.

In conjunction with this assessment, the following three Post PQ Change (PPQC) applications were reviewed and concluded.

Action ID	Description	Conclusion
PPQC2019-013	Response to Label improvement Plan	Proposed Declaration of Labeling was reviewed and amended based on the product assessment.
PPQC2019-014	Long-term Field Study	The three long-term field studies were reviewed, and findings presented in the WHO Decision Document. The Post PQ requirement for submission of long-term field trials for this product has been satisfied.
PPQC2019-022	New Manufacturing Site	Acceptance of those manufacturing sites identified on the Declaration of Manufacturing Sites dated 5 December 2019 .

Please note that inclusion on the list of prequalified products cannot be construed as WHO approval or endorsement and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure will also lead to removal from the list.

Yours sincerely,

Mr Deus Mubangizi
Unit Head
Prequalification Unit
Regulation and Prequalification Department