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In reply please refer to: V2-447-3/DS/MT/1 Saint Charles, Illinois 60174

États-Unis d'Amérique

Your reference: P-11637, PQ-VCP-2023-0009

30 May 2025

Dear Ms Chowdhury:

## WHO Prequalification Unit – Vector Control Products Assessment Team Letter of Prequalification

WHO Product ID: P-11637

Thank you for your submission received on 18 October 2023 and accepted for assessment on 21 December 2023 expressing Clarke International's interest in participating in the prequalification procedures of vector control products. The review of your company's product dossier for:

• Optica ULV - P-11637

has been completed and it has been found to meet the norms and standards recommended by the World Health Organization (WHO) for space spray 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 product will now be included 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 <a href="https://extranet.who.int/pgweb/vector-control-products">https://extranet.who.int/pgweb/vector-control-products</a>.

Please note that inclusion on the list 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,

Dr Matthias Stahl

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Team Lead, Medicines Assessment (as acting Unit Head, Prequalification Unit)