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Website: <https://www.unfpa.org/suppliers#prequalification>

To: Dongkuk Vietnam

Date: July 31, 2023

Ref: **Notice of Lifting of the Quality Alert issued against male latex condoms manufactured by Dongkuk Vietnam Co., Ltd.**

Dear Mr Lee Su Wang

In March 2019 the WHO/UNFPA Prequalification Programme issued a Quality Alert to Dongkuk Vietnam Co. Ltd., which resulted in its withdrawal from the list of prequalified male latex condom manufacturers as the situation was of immediate public health concern. The UNFPA Prequalification Team had received information that a significant number of condom batches manufactured at Dongkuk Vietnam Co. Ltd. failed to meet the minimum quality requirements. The batches were manufactured during the period of December 2015 and May 2016.

An intensive investigation into the causes of these test failures was undertaken by the WHO/UNFPA Prequalification Programme and the manufacturer, and an onsite inspection of the male latex condom manufacturing processes at the under-mentioned site was conducted by inspectors arranged by the UNFPA Prequalification Team.

Name: Dongkuk Vietnam Co. Ltd
Address: No.10, Thuy Van Industrial Zone, Viet Tri City, Phu Tho Province, Vietnam
Date: 6-8 May 2021

The objective of this inspection was to conduct a detailed review of the manufacturing process, focusing on the critical issues related to the investigation, including current and historic Quality Assurance (QA) data and lot control and homogeneity. As major and minor nonconformities were identified during this inspection, it was decided that another inspection will be carried out, subject to the satisfactory resolution of the CAPA to address these nonconformities, to verify the acceptable implementation of the changes included in the CAPA and that appropriate steps have been taken to reduce short term variability and significantly reduce the risk of further lot failures. Thus, the Quality Alert remained active on the UNFPA website until further notice.

The second onsite inspection was conducted from 23-25 November 2022, by inspectors of the UNFPA Prequalification Team with the primary objective of a further review of implemented CAPAs and to assess the current level of conformity with WHO/UNFPA Prequalification Programme requirements. The factory demonstrated general conformance with the inspection criteria, but there were some repeat nonconformances identified. However, it could still be concluded that there was sufficient evidence to confirm that the changes and improvements made had resulted in an improvement in quality, thereby reducing the associated risk to public health and justifying reinstating Dongkuk Vietnam Co. Ltd. to the list of prequalified male latex condom manufacturers. **The Quality Alert will henceforth be removed from the website and archived.**



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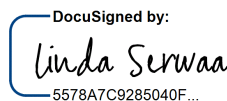
Acceptance of the CAPA implementation arising from the Quality Alert investigation means that Dongkuk Vietnam Co. Ltd. will be reinstated, and remain, on the list of prequalified male latex condom manufacturers while they are addressing the findings made at the recent inspection. You will be notified of the outcome of this reassessment in due course. However, since there were some repeat nonconformities, please note that an onsite verification of the implementation of these nonconformities will be conducted, and if it is not satisfactory, Dongkuk Vietnam Co. Ltd will be issued with a Notice of Concern.

In view of the fact that in previous assessments and inspections related to the Quality Alert issued, a number of major observations were made, we would remind you that the improvements made to date and that the manufacturing site's level of conformity with the WHO/UNFPA Prequalification Programme requirements must be sustained and improved.

You should also draw to the attention of your customers that WHO/UNFPA Prequalification Programme recommends that they conduct an adequate risk analysis during their procurement operations as per their internal procedures. Dongkuk Vietnam Co. Ltd. may therefore reasonably expect an enhanced level of supervision by its customers and should plan to support this in the foreseeable future.

Please do not hesitate to send an email to unfpa.prequalification@unfpa.org should you require any further information regarding the lifting of this Quality Alert and the content of this letter.

Thank you

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Linda Serwaa
Head, Product Quality Assurance and WHO/UNFPA Prequalification
Supply Chain Management Unit