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To: All Stakeholders

Date: September 25, 2020

Ref: **Update to Quality Alert for Male Latex Condom manufacturer – Dongkuk Vietnam Co. Ltd**

Dear Stakeholders

UNFPA would like to provide an update on the status of the quality complaint investigation carried out for Dongkuk Vietnam Co. Ltd. Since the publication of the Quality Alert, a desk review of the manufacturer documentation was done, leading to an inspection that was carried out in May 2019.

The manufacturer has shown great commitment and willingness to diligently address all the findings made at the inspection, and has now satisfactorily resolved all the outstanding issues. QC data submitted by the manufacturer from February 2020 to June 2020 confirm that average burst volumes and pressures are good and within lot and lot to lot variability are under acceptable levels of control. Based on the documents submitted and reviewed, it is evident that the manufacturer has better control of their production process and the risk can be considered as reduced. However, reinstatement into the list of prequalified manufacturers can only be made after an onsite inspection is carried out to verify the CAPA implementation, and to review all the quality related matters and other aspects that could not be covered during the investigation inspection which was focussed on reasons for in-country lot rejections. The re-inspection will be scheduled as soon as travel restrictions permit.

Please do not hesitate to contact us at psb.prequalification@unfpa.org for any clarifications.

Thank you,

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