

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2018-07 Version 2: 28/09/2023	Reinstatement of Dongkuk Viet Nam Co., Ltd. to the WHO/UNFPA list of prequalified male latex condom manufacturer
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Addressees

- Any procurers, buyers

Purpose

The GF QA is issuing this information notice to provide updated information regarding the reinstatement of a manufacturer of male latex condom to the WHO/UNFPA list of prequalified manufacturers.

Identification of the product(s) and manufacturer

Name of Manufacturer	Dongkuk Viet Nam Co., Ltd. No.10, Thuy Van Industrial Zone, Viet Tri city, Phu Tho Province, Viet Nam
Commercial Name(s)	All
Packaging & Pack size & Type	All (Size, Texture, Flavour, Color)
Batch(es)	All
Manufacturing Date	All

Background

UNFPA received information that some batches of male latex condoms manufactured by **Dongkuk Viet Nam Co., Ltd. No.10, Thuy Van Industrial Zone, Viet Tri city, Phu Tho Province (Viet Nam)** failed to meet the expected quality criteria. The information includes a test performed by an independent testing laboratory accredited. Results show a major issue with the condoms failing a critical performance parameter from holes' and burst properties test.

Consequently, and in the interest of public health, UNFPA has suspended the manufacturer from the WHO/UNFPA list of prequalified manufacturers of male latex condom until further notice.

Following an investigation of the quality complaints lodged against Dongkuk Vietnam Co., Ltd, located at No.10, Thuy Van Industrial Zone, Viet Tri City, Phu Tho Province, Vietnam, UNFPA QA team has informed GF QA team that they had lifted the related Quality Alert and that the manufacturer has been reinstated to the list of prequalified male condom manufacturers.

Nature of defect(s)

Details of defect or problem.	NA
Is there any evidence or suspicion of a risk to public health?	NA
Extent of the problem (eg. nb batches).	NA
Extent of distribution of the product / batch (es).	NA
Number of patients potentially impacted	NA

Action/Investigations taken

n/a

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by GF QA:

To resume procurement of male latex condom manufactured by Dongkuk Viet Nam Co., Ltd. while maintaining current practices on registration and reporting of any adverse event/reaction or quality issue.

Contacts

Please direct the respective answers and any questions about this matter to the technical contact listed below

Organisation	Name / Function	E-mail address
Global Fund	Amélie Darmon, QA Specialist	Amelie.darmon@theglobalfund.org
UNFPA	Linda Serwaa, Head, Product Quality Assurance	serwaa@unfpa.org