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Procurement Services Branch, PSB
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E-mail: unfpaprequalification@unfpa.org
Website: <https://www.unfpa.org/suppliers#prequalification>

To: MHL Healthcare Limited

Date: June 23, 2023

Ref: **Notice of Lifting of Notice of Suspension of MHL Healthcare Ltd. from the WHO/UNFPA Prequalification Programme for male latex condoms.**

Dear Dr Puneet Manocha

In January 2020 the WHO/UNFPA Prequalification Programme of male latex condoms issued a Notice of Suspension to remind MHL Healthcare Ltd. of its obligations to procurers and product users but also to inform procurement agencies of potential risks associated with its product, as identified through the reported quality complaints against male latex condoms manufactured by MHL Healthcare Ltd. in March and April 2019 and distributed to Uganda. Additionally, MHL Healthcare Ltd. had ongoing CAPA submission requirements to address the failure of Lot no.17120103, recorded at a prequalification inspection product testing. The situation was of immediate public health concern therefore MHL Healthcare Ltd. was removed from the list of prequalified male latex condom manufacturers.

An investigation was initiated by the WHO/UNFPA Prequalification Programme, and due to the COVID-19 pandemic travel restrictions, a provisional remote (virtual) inspection of the male latex condom manufacturing processes at the under-mentioned site was conducted by inspectors from the UNFPA Prequalification Team.

Name: MHL Healthcare Limited
Address: 3Km. Budhana Road, MuzaffarNagar - 251002 (U.P.), India,
Date: 16-19 November 2021

The objective of this inspection was to assess the manufacturing process and to confirm that the CAPAs agreed during the quality complaint review had been implemented and to carry out a complete prequalification inspection. It was observed that there were no outstanding CAPAs from the previous inspection and those raised during the quality investigation had all been addressed prior to the inspection. However, as there were new critical, major, and minor deviations from the WHO/UNFPA Prequalification Programme requirements identified during this inspection, and the fact that an onsite verification of effective CAPA implementation was not possible as is required for all delisted manufacturers, the NOS remained active on the UNFPA website until further notice.

An onsite inspection was conducted from 12-14 June 2023 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 where satisfactory completion of the previous CAPAs was observed.



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It was confirmed that the CAPAs had been completed to a satisfactory level. The review also took into consideration, the results of an accelerated stability study conforming to the revised protocol, and the QC summary reports to date. It could therefore be concluded that there was sufficient evidence to confirm that the changes and improvements made had resulted in a sufficient improvement in quality, thereby reducing the associated risk to public health and justifying reinstating MHL Healthcare Ltd. to the list of prequalified male latex condom manufacturers. **The NOS will henceforth be removed from the website and archived.**

Please note that acceptance of the CAPA implementation arising from the quality complaint investigation means that MHL Healthcare 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.

In view of the fact that in previous inspections, an NOS was issued, and a number of critical and major observations were made, we would remind you that the improvements made to date and that your level of conformity with the WHO/UNFPA Prequalification Programme requirements must be sustained and improved. The next full inspection of your operations will be performed as per routine programme procedures.

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. MHL Healthcare 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 NOS 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