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on-programme

To: All Stakeholders

Date: January 24, 2022

Ref: Update to UNFPA Prequalification Programme Notice of Suspension for MHL

Healthcare Ltd.

Dear Stakeholders

The UNFPA Prequalification Programme would like to provide an update on the published communication dated July 26 2021.

A remote inspection was carried out at MHL Healthcare Ltd.'s manufacturing site from 16 – 19 November 2021, to verify the implementation of the corrective and preventive actions (CAPAs) in response to the identified causes of the reported non-conformances pertaining to the quality complaint investigation initiated against MHL Healthcare Ltd. A full prequalification inspection was carried out.

The remote inspection confirmed that the CAPAs identified during the quality investigation had been implemented. The prequalification inspection, however, identified further findings that require attention from the manufacturer. Upon submission of a satisfactory CAPA in response to these findings, the decision to prequalify the manufacturer will be made.

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

Thank you

Docusigned by:

Seloi Mogatle

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Seloi Mogatle Head, Quality Assurance