World Health Organization

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In reply please refer to: PQT-PM/sm (2020-127)

Your reference:

Mr Ahmed Adel Khalil
International Company for Medical Necessities
Industrial Zone
Block No. 19&67 Abu Tig
Assuit
Egypte

2 June 2020

Dear Mr Ahmed Adel Khalil,

Notice of revalidation for single use injection devices

Thank you for having submitted the complete dossiers for revalidation during the 2020 annual review (AR) of single use injection devices. These devices are currently listed in the Prequalification (PQ) database with the following codes E008/124, E013/115, E013/116, E013/117.

We are pleased to inform you that these products are re-validated until 31 May 2021 and will be published accordingly in the PQ WHO website page:

http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

We will formally notify you of the date of next year's review.

If any of your time bound certificates expire before May 2021, you are requested to provide us with the new documents at their time of issue.

Kindly note that although PQ does not explicitly call for active monitoring, we do require notification of adverse events and device failures in accordance with our agreement under the terms and conditions of the PQ scheme.

Kindly note:

- The focus of the PQ is progressing from a qualification process based on certificate and license reviews, towards the improvement of products through manufacturing change transparency, CAPAs with more detailed failure reports and risk mitigation.
- A pre-review of submissions will take place four weeks before the Annual Review (on or shortly after the submission deadline). Should the manufacturer be required to provide further information or to complete documentation, they will be advised two to three weeks prior to the AR.
- Reminders:
  - *Confidentiality*: all information provided by the manufacturer will be treated in the strictest confidence.
  - *Licence/certificate renewal*: manufacturers are requested to ensure business licences and manufacturing certificates are valid and, when renewal is required, to ensure that valid documents are provided to the PQS Secretariat in line with the AR submission deadline.

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- *Certification validation*: manufacturers are reminded that they are obliged to provide a web-link to a certificate authentication page for each mandatory certificate.
- *Manufacturer declaration*: manufacturers are reminded of the requirement to sign and date the Manufacturer Declaration form in order to validate their submission. Products cannot be recommended for re-validation in the absence of this signature.
- *Fees payment*: Payment of the previous years' fee is required for a manufacturer to have its products re-validated in the subsequent AR. Payment of fees is verified.

Yours sincerely,

Mr Paul Mallins
Technical Officer
Vaccines & Immunization Devices Assessment Team
Prequalification Unit