World Health Organization

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In reply please refer to: CC/vl

Your reference: P17-370-9

SD Biosensor, Inc
Attention: Mr Young-Gyun Kim
C 4th and 5th, 16 Deogyeong-daero, 155 beon-gil
Suwon-si, Geonggi-do
16690
République de Corée

26 May 2020

Dear Mr Kim,

Subject: WHO Prequalification of In Vitro Diagnostics – Final Public Report

Product name: STANDARD Q HIV/Syphilis Combo Test
Product codes: 09HIV20D
Regulatory version: Rest-of-World regulatory version
Manufacturer: SD Biosensor Inc
PQDx Reference Number: PQDx 0382-117-00

We are pleased to inform you that the above-referenced product was prequalified on 26 May 2020 and listed on the World Health Organization (WHO) list of prequalified in vitro diagnostic products.

Please be advised that the on-going prequalification status of the above-referenced product depends on fulfilling the following commitment to prequalification with regard to issues identified during the WHO prequalification assessment. The commitment is, "*to provide the interim study report and raw data for device stability studies on 24 November 2020 and the final report and raw data on the 23 March 2022".*

The following post-prequalification activities are required to maintain the prequalification status:

1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic*" (document number PQDx_121); and
2. Post-market surveillance activities, in accordance with "*WHO guidance on post-market surveillance of in vitro diagnostics*" (ISBN 978 92 4 150921 3).

You are also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents. The sales data will serve as denominator data to guide the frequency of re-inspection.

Failure to comply with any of the above-mentioned post-prequalification requirements may lead to remedial action by WHO, including but not limited to, de-listing from the WHO list of prequalified in vitro diagnostic products.

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+4122 791 5891).

Yours sincerely,

Mr Deus Mubangizi
Unit Head
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and other Health Products Division