

20, AVENUE APPIA - CH-1211 GENEVA 27 - SWITZERLAND - TEL CENTRAL +41 22 791 2111 - FAX CENTRAL +41 22 791 3111 - WWW.WHO.INT

 Tel. direct:
 +41 22 791 5891

 Fax direct:
 +41 22 791 4836

 E-mail :
 diagnostics@who.int

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 postmarket 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,

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