



Health Sciences Authority



PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Medical Device Device Category Registrant Product Owner Importer Wholesaler Advanced Search

Device Info

Device Name: **SD BIOLINE HIV Ag/Ab Combo** [Standard Diagnostics Inc]

Description: The SD BIOLINE HIV Ag/Ab Combo is a rapid, qualitative test for the detection of HIV p24 antigen and antibodies to all isotypes (IgG, IgM and IgA) specific to HIV-1 including subtype O and/or HIV-2 simultaneously in human serum, plasma or whole blood. The SD BIOLINE HIV Ag/Ab Combo Rapid test kit is for in vitro use and intended for professional use. This kit is intended only for an initial screening test and reactive samples should be confirmed by a supplemental assay such as ELISA or Western Blot test.

Medical Specialty Area: Microbiology

HS Code: 38220090

HSA Product code: HSAMDD00106

Medical Device Class: Class D IVD

Device Registration No: DE0014266

Registration Date: 08/11/2013

Change Notification Approval Date: Not Applicable

Expiry Date: 07/11/2014

Product Owner

- [Standard Diagnostics Inc](#) [Standard Diagnostics Inc] 65 Borahagal-ro, Giheung-gu,, Yongin-si, Gyeonggi-do, Korea, K...

Registrant

- [UNISON COLLABORATIVE PTE. LTD.](#) 400 ORCHARD ROAD, ORCHARD TOWERS, #12-05, SINGAPORE 238875

Imported By

- [UNISON COLLABORATIVE PTE LTD](#) [ES0001236] 400 ORCHARD ROAD, ORCHARD TOWERS, #12-05, SINGAPORE 238875

Models

Product Code for Accessories:

No.	Model Name	Identifier
1	SD Bioline HIV Ag/Ab Combo	03FK30
2	SD Bioline HIV Ag/Ab Combo	03FK35

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Legend:

^ Suspended Medical Device.

