Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311989	Atomo Diagnostics Pty Ltd - Atomo HIV self test - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

ARTG entry for	Medical Device Included - IVD Class 4
Sponsor	Atomo Diagnostics Pty Ltd
Postal Address	701 - 703 Parramatta Road, LEICHHARDT, NSW, 2040 Australia
ARTG Start Date	28/11/2018
Product category	Medical Device Class 4
Status	Active
Approval area	IVD

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Atomo Diagnostics Pty Ltd	Level 2 701 - 703 Parramatta Road LEICHHARDT, NSW, 2040 Australia

Products

1. Atomo HIV self test - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

Product Type	IVD	**Effective date**	28/11/2018

GMDN	48454 HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid
Functional description	The Atomo HIV Self Test is a single-use, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus (HIV) Type 1 and Type 2 in whole blood.
Intended purpose	The Atomo HIV Self Test is a single-use, immunochromatographic, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus (HIV) Type 1 and Type 2 in whole blood. The device is intended to be used by untrained lay users as a self test to aid in the diagnosis of infection with HIV-1 and HIV-2 from samples of fresh, whole blood obtained through a finger stick blood collection technique. The test result is qualitative and not for screening blood donors.
Variant information	

Specific Conditions

1. The person Atomo Diagnostics Pty Ltd in relation to whom the Atomo HIV self test (the device) is included in the Australian Register of Therapeutic Goods (the ARTG) must ensure that the device is only supplied: a. through on-line channels, to ensure the user views the on-line instructional video prior to using the test, and b. to organisations that: i. employ healthcare workers who have received training in the delivery and administration of HIV testing in accordance with the requirements of the National HIV Testing Policy and ii. have an established relationship (in relation to the referral and testing of specimens) with a NATA accredited medical testing laboratory.
2. The sponsor of the Atomo HIV self test must make available to each organisation identified in 1b, training in the correct use of the device and interpretation of results.
3. The sponsor of the Atomo HIV self test must provide HIV telephone helpline operators providing 24 hour customer support, training in the correct use of the device and interpretation of results.
4. The sponsor of the Atomo HIV self test must ensure HIV telephone helpline operators providing 24 hour customer support have received training in the delivery and administration of HIV testing in accordance with the requirements of the National HIV Testing Policy.
5. The sponsor must maintain records that demonstrate that the device has been supplied in compliance with condition 1 and that it has complied with condition 2, 3 and 4.
6. The sponsor must provide a copy of the final version of the patient care card that is to be supplied with the device to the TGA within six (6) months from the date of inclusion of the device in the ARTG or no later than 30 June 2019.
7. The sponsor must provide to the Therapeutic Goods Administration (TGA) a post market surveillance report for each reporting period commencing on the date of inclusion of the device in the ARTG and ending at the end of the next 30 June and each twelve (12) months thereafter for the next (5) financial years. Reports must be provided to the TGA before 1 October after each reporting period and must include the following a. Numbers of tests sold in Australia and Worldwide b. Any adverse events including numbers of any reported false positive or false negative results in Australia and Worldwide. c. Reported problems or complaints associated with the use/interpretation of the device in Australia and Worldwide.
8. Post-market reports must be sent to the TGA at the following email address postmarketdevices@health.gov.au

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This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

Visit www.tga.gov.au for contact information

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