Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311989	Atomo Diagnostics Limited - 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 Limited
Postal Address	Level 1 3-5 George Street, 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 Limited	Level 1 3-5 George Street 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

Supply
(1) The person in relation to whom the Atomo HIV Self Test (the device) is included in the Australian Register of Therapeutic Goods (the sponsor) must ensure that the device is only supplied to one or more of the following
(a) a business, organisation or institution (including a pharmacy) that employs or engages individuals who have received appropriate training (in any form) in relation to the correct use and performance of the device, and the interpretation of the test result
(b) a person directly through the website of the sponsor or a pharmacy

Customer support services
(2) The sponsor must publish on its website a simple, clear and effective instructional video, demonstrating the correct use and performance of the device, and the interpretation of the test result

(3) The sponsor must
(a) provide information about relevant support services and confirmatory testing available in each state and territory with the supply of each device and
(b) publish the information mentioned in paragraph (a) on its website

(4) The sponsor must take steps to ensure that a business, organisation or institution (including a pharmacy) mentioned in condition (1)(a), or a pharmacy mentioned in condition (1)(b), has access to, and encourages the dissemination of, the following by any means
(a) information about the correct use and performance of the device, and the interpretation of the test result, consistent with the information provided in the instructional video mentioned in condition (2) and
(b) information about the support services and confirmatory testing mentioned in condition (3)

(5) The sponsor must provide a telephone helpline that
(a) provides customer support about the correct use and performance of the device, and the interpretation of the test result and
(b) operates (as a minimum) between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week

(6) The sponsor must ensure that the operators providing customer support services mentioned in condition (5) have received training in the delivery and administration of HIV testing, in accordance with the requirements of the National HIV Testing Policy (which may be accessed via the ASHM website at www.ashm.org.au)

Post market surveillance reports
(7) The sponsor must provide a post market surveillance report, containing the following information, to the Therapeutic Goods Administration (at the email address postmarketdevices@health.gov.au) for each reporting period specified in condition (8), before 1 October after that reporting period
(a) the numbers of tests sold both in Australia and overseas
(b) any adverse events, including numbers of any reported false positive or false negative results, both in Australia and overseas
(c) reported problems, issues or complaints associated with the use or interpretation of the device, both in Australia and overseas

(8) Each of the following is a reporting period
(a) the period beginning on the day when this condition is imposed, and ending at the end of the next 30 June
(b) each of the next five financial years.

Record keeping
(9) The sponsor must maintain records that demonstrate that the sponsor has complied with each of the conditions mentioned above (relating to supply, customer support services and post market surveillance reports) and provide those records to the Secretary on request.

Public Summary