



## **Repealed - Therapeutic Goods (Prohibited Representations—HIV Self-Test Fact Sheet) Permission 2019**

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I, Gillian Mitchell, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 15 February 2019

Gillian Mitchell  
First Assistant Secretary  
Regulatory Practice and Support Division  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Prohibited Representations—HIV Self-Test Fact Sheet) Permission 2019*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is made.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 42DK(3) of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) device number;
- (b) included in the Register;
- (c) medical device; and
- (d) Register.

In this instrument:

**Act** means *Therapeutic Goods Act 1989*.

**AFAO** means the Australian Federation of Aids Organisations (ABN 91 708 310 631).

**Atomo HIV Self Test** means the Class 4 IVD medical device, *Atomo HIV self test – HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid* (device number 311989), included in the Register with the commencement date 28 November 2018.

**Class 4 IVD medical device** has the same meaning as in the Regulations.

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***HIV Self-Test Fact Sheet*** means the document in Schedule 1 to this instrument.

***prohibited representation*** has the same meaning as in subsection 42DJ(1) of the Act.

***Regulations*** means the *Therapeutic Goods (Medical Devices) Regulations 2002*.


## **5 Permission**

For subsection 42DK(3) of the Act, in relation to each item, the prohibited representations specified in column 2 of the table in Schedule 2 to this instrument are permitted to be used in an advertisement specified in column 3 of the table, about the therapeutic goods specified in column 4 of the table, subject to the conditions (if any) specified in column 5 of the table.

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# Schedule 1—HIV Self-Test Fact Sheet

Note: See section 4, definition of *HIV Self-Test Fact Sheet*.



## HIV SELF-TEST FACT SHEET

On 28 November 2018, the first HIV self-testing device (the Atomo HIV Self-Test) was approved for sale in Australia for the first time. The HIV self-test is expected to be available for sale in late March 2019.

### WHO SHOULD BE TESTING FOR HIV?

HIV testing is appropriate for anyone who may have been exposed to HIV. HIV exposure can occur through sexual contact without the use of an effective HIV prevention strategy (such as treatment as prevention, PrEP or condoms), sharing of needles or exposure to bodily fluids such as blood. HIV cannot be transmitted through casual contact such as hugging, kissing, or other skin to skin contact.

The people listed below should consider routine, regular HIV and sexually transmitted infection (STI) testing:

- gay and bisexual men and other men who have sex
- trans and gender diverse people
- people who inject drugs
- people who have multiple partners
- sexual and injecting partners
- people who are from high prevalence areas

It is recommended that you get tested for HIV and STI.

### HOW ACCURATE IS THE TEST?

The HIV self-test has been shown in trials to identify 99.6% of HIV negative and 99.9% of HIV positive people.

Like other HIV tests, the self-test is a screening test. For the HIV self-test, you will need to be confirmed with further testing by a doctor. This means that the self-test is not a definitive test. This means that the self-test is not a definitive test. This means that the self-test is not a definitive test.

If you think you may have HIV, you should get tested. If you think you may have HIV, you should get tested. If you think you may have HIV, you should get tested.

The self-test is available for purchase online. You will be required to watch a video on the proper use of the test prior to purchase. The self-test is available for purchase online. You will be required to watch a video on the proper use of the test prior to purchase. The self-test is available for purchase online. You will be required to watch a video on the proper use of the test prior to purchase.

The self-test can also be distributed or sold by organisations such as community health centres, sexual health clinics, and community councils. You can find a list of relevant local organisations to contact for more information on receiving a HIV self-test [here](#).

### WHAT HAPPENS IF I GET A POSITIVE RESULT?

While the self-test is very accurate, it is still a screening test. Because it is a screening test, getting a positive result does not necessarily mean you have HIV. If you have received a positive result on the self-test, it will still need to be confirmed with further testing by a doctor. You can refer to the enclosed Care Card for more information about accessing follow-up testing.

If you receive a positive result with the follow-up testing, it is important that you speak to a doctor about starting treatment. HIV is a manageable condition, treatment today is very effective and those living with HIV are able to live long and healthy lives.

For more information on HIV self-testing please contact AFAO on (02) 9557 9399

### HOW DOES IT WORK?

The test is a finger-prick blood test. The result is provided within fifteen minutes after performing the test.

LAST UPDATED: 12 FEBRUARY 2019

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## Schedule 2—Permission

Note: See section 5.

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### Permitted use of prohibited representation

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Column 1	Column 2	Column 3	Column 4	Column 5
Item	Prohibited representation	Advertisement	Therapeutic goods	Condition
1	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to: (a) sexually transmitted diseases; and (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)	HIV Self-Test Fact Sheet	Atomo HIV Self Test	

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