

# Repealed - Therapeutic Goods (Prohibited Representations—HIV Self-Test Fact Sheet) Permission 2019

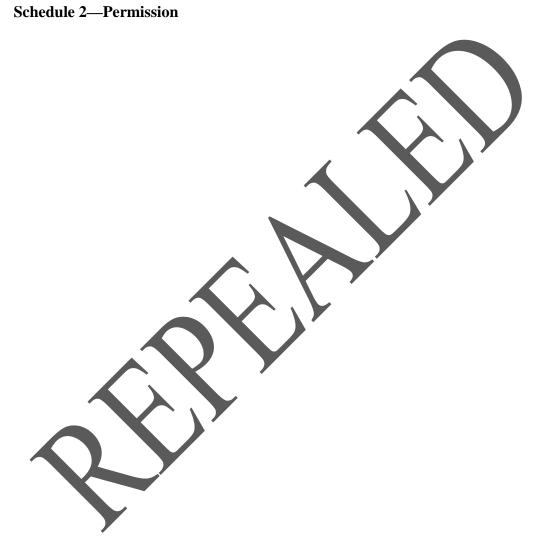
I, Gillian Mitchell, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 15 February 2019

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

# Contents

Schedule 2—		· -
Schedule 1—	HIV Self-Test Fact Sheet	4
	5 Permission	.3
	4 Definitions	
	3 Authority	
	2 Commencement	.2
	1 Name	.2
0 0 11 0 11 0 2		



#### 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 i	nformation	
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is m	rade.

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This table relates only to the provisions of this instrument as originally made.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.

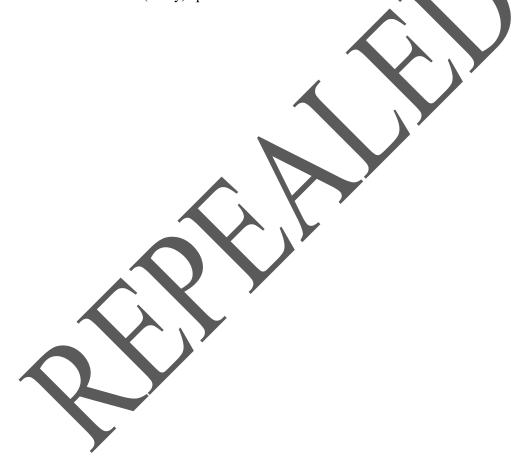
Class 4 IVD medical device has the same meaning as in the Regulations.

*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.



## Schedule 1—HIV Self-Test Fact Sheet

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



## **HIV SELF-TEST FACT SHEF**

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 sey
- · trans and gender diverse people
- · people who inject drugs
- · people who have multiple partne
- sexual and injecting partner
- · people who are from high prevalence

It is recomm and STIr

> ₁e HIV co use. ead your result

ig a paper test strip. It is When it is made available in include an HIV self-test cartridge. cest fluid (which is added along with a ag, and a Care Card with a list of contacts aons or concerns about the test or your result.

y only one test approved for sale in Australia. the Atoms. Jelf-Test. It is important to only buy devices approved for sale, so you can be sure the result is accurate and that the device is safe to use.



## HOW DOES IT WORK?

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

HOW ACCURATE IS THE TEST?



⊿ for purchase online. You will be required i video on the proper use of the test prior to

can also be distributed or sold by organisations such Louncils. You can find a list of relevant local organisations to uss 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 selftest, 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

LAST UPDATED: 12 FEBRUARY 2019

## **Schedule 2—Permission**

Note: See section 5

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 predisposition to:	HIV Self-Test Fact Sheet	Atomo HIV Self Test	
	(a) sexually transmitted diseases; and			
	(b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)			