Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Pharma Soul Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	374627
ARTG Start Date	14/09/2021
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	The PixoTest® COVID-19 Ag Test Kit is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 present in human nasopharynx cavity. The PixoTest® COVID-19 Ag Test Kit is designed to be used in conjunction with the PixoTest® POCT Analyser for the issuing of fully digitalised rapid SARS-CoV-2 test results. This test is single use only and the administration of the test and the interpretation of the results should be done by trained healthcare professionals only. The result of this test should not be the sole basis for the diagnosis of COVID-19; additional confirmatory testing is required.

Manufacturer Details	Address	Certificate number(s)
iXensor Co Ltd	6F No 9 Aly 2 Ln 35 Jihu Rd Neihu Dist , Taipei City , 11492 Taiwan	DV-2021-MC-16183-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Severe acute respiratory syndrome-associated coronavirus IVDs

This entry: contains System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
PixoTest® COVID-19 AG Test Kit	Point of care testing

Product Specific Conditions

· (1) The person in whose name the device is included in the Register (the sponsor) may only supply the device to one or more of the following: (a) a laboratory that is an accredited pathology laboratory within the meaning of the Health Insurance Act 1973
(b) a medical practitioner who is registered under a law of a state or territory to practice medicine, a person registered under a law of a state or territory to practice paramedicine (a paramedic), or an organisation, business or institution that employs or engages a medical practitioner or a paramedic,

where
(i) the medical practitioner or the paramedic is responsible for performing or supervising the performance of the test and
(i) the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result and
(ii) the device is only used to test employees or contractors of the organisation, business or institution or a patient under the direct care of the medical practitioner or the paramedic
(c) a residential care or aged care facility, or a home care service provider, that employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989 or a paramedic (as defined in paragraph (b)), where
(i) the health practitioner or the paramedic is responsible for performing or supervising the performance of the test and
(ii) the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result and
(iii) the device is only used to test residents, employees or contractors of, or visitors to, the residential care or aged care facility, or clients, employees, or contractors of the home care service provider (d) an organisation, business or institution that employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989 or a paramedic (as defined paragraph (b)) where
(i) the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
(ii) the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result and
(iii) the device is only used to test employees, contractors or students of the organisation, business or institution, or a person who is a patient of a practitioner registered under a law of the state or territory to practice dentistry and who requires an emergency dental procedure
(e) a department of the Commonwealth, state or territory, with responsibility for health, or a department or other agency of the Commonwealth, state or territory acting on its behalf.

- (2) The device must not be supplied for the purpose of self-testing.
- (3) The sponsor of the device must provide training to a person mentioned in subparagraphs (1)(b)(ii), (1)(c)(ii), (1)(d)(ii) or (1)(e) in the correct use of the device and the interpretation of the test result, prior to that person performing or supervising the performance of the test.
- (4) The sponsor must maintain records that demonstrate the device has been supplied in compliance with these conditions.

And within 12 months of an approval the following information will be required to be provided to the TGA.

- (5) A report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide.
- (6) Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions.
- (7) Further analytical and clinical evidence to support
  (a) Analytical and clinical performance of the device
  (b) Device stability (e.g, shelf-life stability, transport stability)
- (8) Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.
- (9) Evidence of how the user may verify, at the time of use that the device will perform as intended by the manufacturer through the use of controls.