



Australian Register of Therapeutic Goods Certificate

Issued to

Nia Pharmaceuticals Pty Ltd

for approval to supply

Clinical chemistry hormone IVDs

ARTG Identifier	352653
ARTG Start Date	7/01/2021
Product Category	Medical Device Included - IVD Class 2
GMDN	CT850
GMDN Term	Clinical chemistry hormone IVDs
Intended Purpose	In vitro diagnostic visual qualitative immunochromatographic test intended for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

Manufacturer Details	Address	Certificate number(s)
Alfa Scientific Designs Inc	13200 Gregg Street POWAY , CA , 92064 United States Of America	DV-2019-MC-02909-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 2 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. Clinical chemistry hormone IVDs

This entry: does not contain System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
Instant-view Pregnancy Urine Cassette Test	Point of care testing
Instant-view One Step Pregnancy Test	Self Testing

Product Specific Conditions

No specific conditions have been recorded against this entry.

