



Australian Register of Therapeutic Goods Certificate

Issued to

Elitechgroup Australia Pty Ltd

for approval to supply

Viral infectious disease IVDs

ARTG Identifier	310921
ARTG Start date	30/10/2018
Product Category	Medical Device Included - IVD Class 2
GMDN	CT355
GMDN Term	Viral infectious disease IVDs
Intended Purpose	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of viral diseases.

Manufacturer Details	Address	Certificate number(s)
Serosep Limited	Annacotty Business Park Annacotty Co Limerick, , Ireland	DV-2015-MC-20430-1

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. Viral infectious disease IVDs

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

Product Specific Conditions

No specific conditions have been recorded against this entry.