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

<table>
<thead>
<tr>
<th>Address</th>
<th>Certificate number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serosep Limited</td>
<td>DV-2015-MC-20430-1</td>
</tr>
<tr>
<td>Annacotty Business Park</td>
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<td>Annacotty</td>
<td></td>
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<tr>
<td>Co Limerick, Ireland</td>
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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.

 Therapeutic Goods Administration
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