**Australian Register of Therapeutic Goods Certificate**

**Issued to**

ConMed Linvatec Australia Pty Ltd

**for approval to supply**

Skin - ConMed Linvatec Australia Pty Ltd

**ARTG Identifier** 299299

**ARTG Start date** 2/02/2018

**Product Category** Biological Included Class 2

**Intended Use**

1. Replacement of damaged or inadequate integumental tissue, or reinforcement of soft tissue defects
2. Replacement of damaged or inadequate integumental tissue, or reinforcement of soft tissue defects

<table>
<thead>
<tr>
<th>Manufacturer Details</th>
<th>Address</th>
<th>Manufacturing Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculoskeletal Transplant Foundation</td>
<td>1232 Mid Valley Drive Jessup, Pennsylvania, 18434-1823 United States Of America</td>
<td>Testing - Analytical/Biological</td>
</tr>
<tr>
<td>Musculoskeletal Transplant Foundation</td>
<td>1175 Mid Valley Drive Olyphant, Pennsylvania, 18447 United States Of America</td>
<td>Testing - Analytical/Biological</td>
</tr>
<tr>
<td>Musculoskeletal Transplant Foundation * Principal Manufacturer</td>
<td>Suite 300 / 125 May Street Edison, NJ, 08837 United States Of America</td>
<td>Processing Storage on site Testing - Analytical Packaging and labelling Release for supply</td>
</tr>
<tr>
<td>Nelson Laboratories LLC</td>
<td>6280 South Redwood Road Salt Lake City, UT, 84104 United States Of America</td>
<td>Testing microbial</td>
</tr>
<tr>
<td>VRL Eurofins</td>
<td>6665 S Kenton Street Suite 205 Centennial, Colorado, 80111 United States Of America</td>
<td>Virology Screening and Syphilis Testing NAT Testing for HIV, HCV and HBV</td>
</tr>
</tbody>
</table>

**ARTG Standard Conditions**

The above Biological Included Class 2 has been entered on the Register subject to the following conditions:

No conditions have been recorded against this entry.

**Products Covered by This Entry**

**1. Dermis, Freeze dried - L - AlloPatchHD**

<table>
<thead>
<tr>
<th>Container Type</th>
<th>Container Material</th>
<th>Container Condition</th>
<th>Container Closure</th>
<th>Shelf Life Time</th>
<th>Shelf Life Temperature</th>
<th>Shelf Life Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pouch</td>
<td>Other plastic laminate/Al</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>3 Years</td>
<td>Room temperature</td>
<td>Store at room temperature Do not Freeze Do not Refrigerate</td>
</tr>
</tbody>
</table>

**Product Specific Conditions**

- If a good that is distributed overseas is the same as a good that is included in the Register and supplied...
in Australia, any product recall or similar regulatory action taken in relation to the good outside Australia that concerns, or is related to, the quality, safety or efficacy of the good, must be notified to the Secretary by the sponsor of the good as soon as the sponsor becomes aware of the action. For this purpose, the Secretary is taken to have been notified when the information is forwarded to the Post-market Surveillance Branch at the TGA either by email at adr.reports@tga.gov.au or via online report forms provided on the TGA website.

- The actual date of commencement of supply of the good after inclusion under Part 3-2A of the Act must be notified to the Director, Biological Sciences Section of the TGA. Please note the definition of ‘supply’ in subsection 3(1) of the Act for this purpose.
- The sponsor must keep records of the supply and distribution of the good for a period of ten (10) years after the distribution of the good.
- Any variations or changes to the good cannot be implemented without either the approval of the Secretary under section 9D of the Act to vary the product's entry in the ARTG or through a change to a condition.

2. Dermis - L - AlloPatchHD

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Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

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