Australian Register of Therapeutic Goods Certificate

Issued to
ConMed Linvatec Australia Pty Ltd
for approval to supply

Musculoskeletal Tissue - ConMed Linvatec Australia Pty Ltd

**ARTG Identifier**  299298
**ARTG Start date**  2/02/2018
**Product Category** Biological Included Class 2

**Intended Use**

1. Treatment of musculoskeletal disorder/disease/trauma
2. Treatment of musculoskeletal disorder/disease/trauma
3. Treatment of musculoskeletal disorder/disease/trauma
4. Treatment of musculoskeletal disorder/disease/trauma
5. Treatment of musculoskeletal disorder/disease/trauma
6. Treatment of musculoskeletal disorder/disease/trauma
7. Treatment of musculoskeletal disorder/disease/trauma
8. Treatment of musculoskeletal disorder/disease/trauma
9. Treatment of musculoskeletal disorder/disease/trauma
10. Treatment of musculoskeletal disorder/disease/trauma
11. Treatment of musculoskeletal disorder/disease/trauma
12. Treatment of musculoskeletal disorder/disease/trauma

**Manufacturer Details**

<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>Storage on site Processing Release for supply Packaging and labelling 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 Release for supply Testing - Analytical Packaging and labelling Storage on site</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 Storage on site</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. Bone, Morsellised, Freeze dried - L
<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>Jar/Can</td>
<td>Plastic</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>
<tr>
<td>Pouch</td>
<td>Plastic</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>3 Years</td>
<td>Room temperature</td>
<td>Store at room temperature</td>
</tr>
</tbody>
</table>

**Product Specific Conditions**

- The ongoing 5 year stability studies being conducted according to the approved protocol outlined in Validation -1505 "Package Stability Study Protocol for the Frozen Triple Layer Packaging" dated 16/8/17, must be completed for confirmation of shelf-life for musculoskeletal tissue in triple layer packaging at below -40°C. Any out of specification results arising from the studies must be immediately notified to the TGA with an accompanying investigative report and corrective/preventative action plan.

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- 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. **Fascia lata, Frozen - L**

<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>Composite plastic laminate</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>5 Years</td>
<td>Store below minus 40 degrees Celsius</td>
<td>Store in a deep freeze, Do not Refrigerate</td>
</tr>
</tbody>
</table>

**Product Specific Conditions**

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3. **Bone, Segmented, Freeze dried - L**

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<tr>
<th>Container Type</th>
<th>Container Material</th>
<th>Container Condition</th>
<th>Container Closure</th>
<th>Shelf Life Time</th>
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<th>Shelf Life Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pouch</td>
<td>Plastic</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>3 Years</td>
<td>Room temperature</td>
<td>Store at room temperature</td>
</tr>
<tr>
<td>Blister</td>
<td>Plastic</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>3 Years</td>
<td>Room</td>
<td>Store at room temperature</td>
</tr>
</tbody>
</table>
Product Specific Conditions

- The ongoing 5 year stability studies being conducted according to the approved protocol outlined in Validation -1505 "Package Stability Study Protocol for the Frozen Triple Layer Packaging" dated 16/8/17, must be completed for confirmation of shelf-life for musculoskeletal tissue in triple layer packaging at below -40°C. Any out of specification results arising from the studies must be immediately notified to the TGA with an accompanying investigative report and corrective/preventative action plan.
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4. Bone, Segmented, Frozen - L

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<tbody>
<tr>
<td>Pouch</td>
<td>Composite plastic laminate</td>
<td>Not recorded</td>
<td>5 Years</td>
<td>Store below 40 degrees Celsius</td>
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<th>Shelf Life Temperature</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Jar/Can Glass Type I Clear</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>
<td></td>
</tr>
<tr>
<td>Jar/Can Glass Type III Clear</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>
<td></td>
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6. Tendon with Bone, Freeze dried - L

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<tr>
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<th>Container Material</th>
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<th>Shelf Life Time</th>
<th>Shelf Life Temperature</th>
<th>Shelf Life Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jar/Can</td>
<td>Glass Type I Clear</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>3 Years</td>
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<tr>
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</tr>
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<tbody>
<tr>
<td>Jar/Can</td>
<td>Glass Type I Clear</td>
<td>Not recorded</td>
<td>Not recorded</td>
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<td>Room temperature</td>
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### 8. Bone, Morcellised, Demineralised, Freeze dried - L

<table>
<thead>
<tr>
<th>Container Type</th>
<th>Container Material</th>
<th>Container Condition</th>
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<th>Shelf Life Time</th>
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<th>Shelf Life Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jar/Can</td>
<td>Plastic</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>3 Years</td>
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### 9. Meniscus with Bone, Frozen - L

<table>
<thead>
<tr>
<th>Container Type</th>
<th>Container Material</th>
<th>Container Condition</th>
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<th>Shelf Life Time</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Pouch</td>
<td>Composite plastic laminate</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>5 Years</td>
<td>Store below minus 40 degrees Celsius</td>
<td>Store in a deep freeze Do not Refrigerate</td>
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### 10. Tendon, Frozen - L
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11. Tendon with Bone, Frozen - L

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Pouch</td>
<td>Composite plastic laminate</td>
<td>Not recorded</td>
<td>Not recorded</td>
<td>5 Years</td>
<td>Store below minus 40 degrees Celsius</td>
<td>Store in a deep freeze Do not Refrigerate</td>
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12. Meniscus, Frozen - L

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Product Specific Conditions

- The ongoing 5 year stability studies being conducted according to the approved protocol outlined in Validation -1505 "Package Stability Study Protocol for the Frozen Triple Layer Packaging" dated 16/8/17, must be completed for confirmation of shelf-life for musculoskeletal tissue in triple layer packaging at below -40°C. Any out of specification results arising from the studies must be immediately notified to the TGA with an accompanying investigative report and corrective/preventative action plan.
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.

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