Australian Government

Department of Health

Therapeutic Goods Administration

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

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

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Jar/Can	Plastic	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate
Pouch	Plastic	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature

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.

2. Fascia lata, Frozen - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Composite plastic laminate	Not recorded	Not recorded	5 Years	Store below minus 40 degrees Celsius	Store in a deep freeze Do not Refrigerate

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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3. Bone, Segmented, Freeze dried - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Plastic	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature
Blister	Plastic	Not	Not	3 Years	Room	Store at room

Pack		recorded	recorded		temperature	temperature Do not Freeze Do not Refrigerate

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

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Composite plastic laminate	Not recorded	Not recorded	5 Years	Store below 40 degrees Celsius	Store in a deep freeze Do not Refrigerate

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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5. Fascia lata, Freeze dried - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Jar/Can	Glass Type I Clear	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate
Jar/Can	Glass Type III Clear	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate

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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6. Tendon with Bone, Freeze dried - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Jar/Can	Glass Type I Clear	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate

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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7. Tendon, Freeze dried - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Jar/Can	Glass Type I Clear	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate

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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8. Bone, Morcellised, Demineralised, Freeze dried - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Jar/Can	Plastic	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate

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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9. Meniscus with Bone, Frozen - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Composite plastic laminate	Not recorded	Not recorded	5 Years	Store below minus 40 degrees Celsius	Store in a deep freeze Do not Refrigerate

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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10. Tendon, Frozen - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Composite plastic laminate	Not recorded	Not recorded	5 Years	Store below minus 40 degrees Celsius	Store in a deep freeze Do not Refrigerate

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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11. Tendon with Bone, Frozen - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Composite plastic laminate	Not recorded	Not recorded	5 Years	Store below minus 40 degrees Celsius	Store in a deep freeze Do not Refrigerate

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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12. Meniscus, Frozen - L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Composite plastic laminate	Not recorded	Not recorded	5 Years	Store below minus 40 degrees Celsius	Store in a deep freeze Do not Refrigerate

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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Therapeutic Goods Administration
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ARTG Identifier: 299298
ARTG Start Date: 2/02/2018